AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

11-13-85
Vol. 50 No. 219
Pages 46737-47026

federal register

Wednesday
November 13, 1985

Briefings on How To Use the Federal Register
For information on briefings in Atlanta, GA, and Philadelphia, PA, see announcement on the inside cover of this issue.

Selected Subjects

Air Pollution Control
Environmental Protection Agency

Aviation Safety
Federal Aviation Administration

Banks, Banking
Federal Home Loan Bank Board

Chemicals
Environmental Protection Agency

Drinking Water
Environmental Protection Agency

Endangered and Threatened Species
Fish and Wildlife Service

Hazardous Substances
Environmental Protection Agency

Marine Safety
Coast Guard

Marketing Agreements
Agricultural Marketing Service

Medicaid
Health Care Financing Administration

Pesticides and Pests
Environmental Protection Agency

Public Lands
Land Management Bureau

CONTINUED INSIDE

Selected Subjects

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

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

The **Federal Register** will be furnished by mail to subscribers for $300.00 per year, or $150.00 for 6 months, payable in advance. The charge for individual copies is $1.50 for each issue, or $1.50 for each group of pages as actually bound. Remit check or money order, made payable to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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

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

How To Cite This Publication: Use the volume number and the page number. Example: 50 FR 12345.

Savings and Loan Associations
Federal Home Loan Bank Board

Supplemental Security Income (SSI)
Social Security Administration

Trade Practices
Federal Trade Commission

Vocational Education
Veterans Administration

Water Pollution Control
Environmental Protection Agency

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

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

WHO: The Office of the Federal Register.

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

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

ATLANTA, GA

WHEN: Nov. 21; at 1 pm.
Nov. 22; at 9 am. (identical session)

WHERE: Room LP-7,
Richard B. Russell Federal Building,
75 Spring Street, SW., Atlanta, GA.

RESERVATIONS: Deborah Hogan,
Atlanta Federal Information Center,
Before Nov. 12: 404-221-2170
On or after Nov. 12: 404-331-2170

PHILADELPHIA, PA

WHEN: Dec. 17; at 1 pm.
Dec. 18; at 9 am. (identical session)

WHERE: Room 3306/10
William J. Green, Jr., Federal Building,
600 Arch Street, Philadelphia, PA.

RESERVATIONS:
Laura Lewis,
Philadelphia Federal Information Center,
215-597-1700

Contents

Federal Register
Vol. 50, No. 219
Wednesday, November 13, 1985

The President
PROCLAMATIONS
46737 Alzheimer's Disease Month, National (Proc. 5405)

Executive Agencies

Agricultural Marketing Service
PROPOSED RULES
46773 Papayas grown in Hawaii; hearing

Agriculture Department
See Agricultural Marketing Service; Federal Crop Insurance Corporation.

Bonneville Power Administration
NOTICES
Environmental statements; availability, etc.:
46814 Eugene-Medford transmission line, OR

Coast Guard
PROPOSED RULES
Ports and waterways safety:
46780 Tampa Bay, Hillsborough Bay and approaches, FL; safety zone

Commerce Department
See Economic Development Administration; International Trade Administration.

Consumer Product Safety Commission
NOTICES
46810 Agency information collection activities under OMB review

Defense Department
PROPOSED RULES
Acqnisition regulations:
46796 Contract cost sharing policy

Drug Enforcement Administration
NOTICES
Registration applications, etc.:
46846 Crosstowns Drugs
46846 Medicine Shoppe
46844 Rosen, Stephen Granet, D.D.S.
46846 Skelton's Pavilion Pharmacy
46846 Whaley, Walker Lanier, M.D.

Economic Development Administration
RULES
Financial assistance requirements:
46749 Nonrelocation; interim

Economic Regulatory Administration
NOTICES
Consent orders:
46819 Empire Gas Corp.
Natural gas exportation and importation petitions:
46817 St. Lawrence Gas Co., Inc.
Remedial orders:
46817 Listo Petroleum, Inc.

Education Department
NOTICES
Grants; availability, etc.:
46813 Handicapped individuals; special recreation programs projects
46810 Handicapped research; funding priorities
Meetings:
46814 Accreditation and Institutional Eligibility National Advisory Committee

Energy Department
See Bonneville Power Administration; Economic Regulatory Administration; Federal Energy Regulatory Commission; Hearings and Appeals Office, Energy Department.

Environmental Protection Agency
RULES
Pesticide programs:
46764 Vertebrate control products; product performance requirements
Toxic substances:
46766 Records and reports of allegations of significant adverse reactions to health or environment
Water pollution control:
46880 Drinking water; maximum contaminant levels (MCLs) for volatile synthetic organic chemicals
PROPOSED RULES
Air quality implementation plans; approval and promulgation; various States:
46782 Utah
Toxic substances:
46785 Pentabromoethylbenzene; testing requirements
Water pollution; effluent guidelines for point source categories:
46784 Oil and gas extraction; offshore subcategory; extension of time and notice of workshop
Water pollution control:
46936 Drinking water; maximum contaminant levels (MCLs) for synthetic organic chemicals, inorganic chemicals and microorganisms
46902 Drinking water; maximum contaminant levels (MCLs) for volatile synthetic organic chemicals
47025 Drinking water; maximum contaminant levels (MCLs) for volatile synthetic organic chemicals; data availability and comment period reopened
NOTICES
Meetings:
46829 Science Advisory Board
Pesticides; emergency exemption applications:
46825 Avermectin B_1
Toxic and hazardous substances control:
46825 Toxic Substances Control Act; citizens' petition guidance
Water pollution control; sole source acquifer designations:
46828 Oregon

Federal Aviation Administration
RULES
Airworthiness directives:
46750 McDonnell Douglas

Airworthiness standards, etc.:
46872 Shoulder harnesses in normal, utility, and acrobatic category airplanes
46751 Control zones
46752, 46753 Transition areas (2 documents)
PROPOSED RULES
Airworthiness directives:
46775 Airbus Industrie and Boeing
46776 Boeing
46777 Gates Learjet
NOTICES
Airport noise compatibility program:
46856 Seattle-Tacoma International Airport, WA

Federal Communications Commission
NOTICES
46858 Meetings; Sunshine Act

Federal Crop Insurance Corporation
PROPOSED RULES
46772 Combined crop insurance regulations

Federal Energy Regulatory Commission
RULES
Natural Gas Policy Act:
46758 Ceiling prices for high cost natural gas produced from tight formations; Wyoming; rehearing, etc.
NOTICES
Electric rate and corporate regulation filings:
46821 Baltimore Gas & Electric Co. et al.

Federal Home Loan Bank Board
RULES
Federal Savings and Loan Insurance Corporation:
46739 Preferred stock as regulatory net worth
Mortgage loans, federally related:
46744 State due-on-sale laws, preemption; prepayment penalties prohibition
NOTICES
46829 Agency information collection activities under OMB review (2 documents)
46858 Meetings; Sunshine Act

Federal Maritime Commission
NOTICES
Freight forwarder licenses:
46830 G.S. Engers & Co.

Federal Reserve System
NOTICES
Bank holding company applications, etc.:
46830 First Colonial Banchares Corp.; correction
46830 First Commerce Corp.; correction
46830 Marine Midland Banks, Inc., et al.
46830 Peoples Bancshares Corp. et al.
46831 Swiss Bank Corp. et al.
46831 Wells Fargo & Co.

Federal Trade Commission
RULES
Prohibited trade practices:
46753 Hospital Corporation of America
46757 Wright-Patt Credit Union, Inc.

Fish and Wildlife Service
PROPOSED RULES
Endangered and threatened species:
46797 Large-flowered skullcap

Food and Drug Administration
NOTICES
46832 Dietary characteristics and cancer; request for data and information and announcement of study
Food additive petitions:
46833 Ferro Corp.
46834 INI Agrico, Inc.
Meetings:
46834 Advisory committees, panels, etc.

Health and Human Services Department
See Food and Drug Administration; Health Care Financing Administration; National Institutes of Health; Social Security Administration.

Health Care Financing Administration
RULES
Medicaid:
46760 Eligibility to severely impaired individuals who work and perform substantial gainful activity

Hearings and Appeals Office, Energy Department
NOTICES
Applications for exception:
46820 Cases filed

Housing and Urban Development Department
RULES
Mortgage and loan insurance programs:
46763 Coinsurance for construction or substantial rehabilitation of multifamily housing projects; clarification; effective date
NOTICES
Senior Executive Service:
46835 Performance Review Board; membership

Indian Affairs Bureau
NOTICES
46835 Indian estates affected by old age assistance claims, list; reimbursement

Interior Department
See Fish and Wildlife Service; Indian Affairs Bureau; Land Management Bureau; Reclamation Bureau.

International Trade Administration
NOTICES
Antidumping:
46808 Barbed wire and barbless fencing wire from Argentina
Countervailing duties:
46801 Circular welded carbon steel standard pipe from Venezuela, etc.
46807 Export trade certificates of review
Scientific articles; duty free entry:
46806 Environmental Protection Agency et al.
46806 Interior Department et al.

Justice Department
See Drug Enforcement Administration.

Land Management Bureau
RULES
Special areas:
46770 Choctaw-Chickasaw Nations and Arkansas Drainage Districts; removed

NOTICES
Opening of public lands:
46843 Utah
Meetings:
46844 Grand Junction District Grazing Advisory Board
Sale of public lands:
46843 Utah
Withdrawal and reservation of lands:
46843 California; correction

Libraries and Information Science, National Commission
NOTICES
46859 Meetings; Sunshine Act

Management and Budget Office
NOTICES
46849 Management and operating contracts use (Circular A-49); proposed rescission and request for comments

National Institutes of Health
NOTICES
Recombinant DNA molecules research:
46834 Action under guidelines

Nuclear Regulatory Commission
NOTICES
46848 Agency information collection activities under OMB review (2 documents)
Applications, etc.:
46847 Philadelphia Electric Co.
46848 Rochester Gas & Electric Corp.
Environmental statements; availability, etc.:
46847 Alabama Power Co.
Meetings:
46847 Reactor Safeguards Advisory Committee

Postal Service
NOTICES
46859 Meetings; Sunshine Act

Reclamation Bureau
NOTICES
Environmental statements; availability, etc.:
46844 Westlands Water District, CA

Securities and Exchange Commission
NOTICES
46850 Agency information collection activities under OMB review
Applications, etc.:
46854 Commerzbank Aktiengesellschaft
Self-regulatory organizations; proposed rule changes:
46850 National Association of Securities Dealers, Inc.
46851 Philadelphia Stock Exchange, Inc.

Social Security Administration
RULES
Supplemental security income:
46760 Eligibility to severely impaired individuals who perform substantial gainful activity
PROPOSED RULES
Supplemental security income:
46778 Income for the aged, blind, and disabled; resource limits for conditional payments

Textile Agreements Implementation Committee
NOTICES
Cotton, wool, and man-made textiles:
46809 Israel

Trade Representative, Office of United States
NOTICES
46850 Japan; leather and leather footwear; hearing; extension of time

Transportation Department
See Coast Guard; Federal Aviation Administration.

Veterans Administration
RULES
Vocational rehabilitation and education:
46763 Vocational Rehabilitation and Counseling Service, authority delegation
NOTICES
46857 Agency information collection activities under OMB review

Separate Parts in This Issue

Part II
46872 Department of Transportation, Federal Aviation Administration

Part III
46880 Environmental Protection Agency

Part IV
46936 Environmental Protection Agency

Part V
47025 Environmental Protection Agency

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

CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR

Proclamations:

5405 46737

7 CFR

Proposed Rules:

426 46772

928 46773

12 CFR

561 46739

563 46739

591 46744

13 CFR

309 46749

14 CFR

21 46872

23 46872

39 46750

71 (3 documents) 46751-46753

91 46872

Proposed Rules:

39 (3 documents) 46775-46777

16 CFR

13 (2 documents) 46753, 46757

18 CFR

271 46758

20 CFR

416 46760

Proposed Rules:

416 46778

24 CFR

251 46763

33 CFR

Proposed Rules:

165 46780

38 CFR

21 46763

40 CFR

141 46880

158 46764

162 46764

717 46766

Proposed Rules:

52 46782

141 (3 documents) 46902-47025

142 46902

435 46784

796 46785

799 46785

43 CFR

2780 46770

48 CFR

Proposed Rules

235 46796

50 CFR

Proposed Rules

17 46797

Federal Register
Vol. 50, No. 219
Wednesday, November 13, 1985

Presidential Documents

Title 3—

The President

Proclamation 5405 of November 8, 1985

National Alzheimer's Disease Month, 1985

By the President of the United States of America

A Proclamation

For more than two million Americans with Alzheimer's disease, each day is fraught with fear and frustration. Fear of getting lost in one's own neighborhood; of not recognizing members of one's immediate family; of not being able to perform simple, familiar chores. For the victims of this disease, tying shoes or setting a table can be overwhelming tasks. As our elderly population grows, more and more people will be affected by this malady.

Alzheimer's disease is the major cause of the confusion, erratic behavior, and forgetfulness once believed to be a "normal" part of old age. This "senility" is actually the result of the destruction of certain brain cells.

As the afflicted person loses the ability to function intellectually, the family faces growing emotional, physical, and financial burdens. Eventually, many victims require specialized professional care. Fifty percent of all nursing home residents in America suffer from Alzheimer's disease or other serious, irreversible forms of dementia.

The medical research community is focusing special attention on Alzheimer's disease in an effort to discover its causes and develop effective treatments. Recently, a Department of Health and Human Services task force defined the current state of medical knowledge of Alzheimer's disease and recommended future research directions. Organizations leading this research include the National Institute of Neurological and Communicative Disorders and Stroke; the National Institute on Aging; the National Institute of Mental Health; and the National Institute of Allergy and Infectious Diseases. For Alzheimer's patients and their families, this intensive research is the greatest source of hope.

But until a way to prevent Alzheimer's disease is found, these families need our support and understanding. I commend the superb services provided by voluntary health organizations, notably the Alzheimer's Disease and Related Disorders Association.

To enhance public awareness of Alzheimer's disease, the Congress, by Senate Joint Resolution 65, has designated the month of November 1985 as "National Alzheimer's Disease Month" and authorized and requested the President to issue a proclamation in observance of this month.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim the month of November 1985 as National Alzheimer's Disease Month, and I call upon the people of the United States to observe that month with appropriate observances and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this 8th day of Nov, in the year of our Lord nineteen hundred and eighty-five, and of the Independence of the United States of America the two hundred and tenth.

Ronald Reagan

[FR Doc. 85-27159
Filed 11-12-85; 11:15 am]
Billing code 3195-01-M

Rules and Regulations

Federal Register
Vol. 50, No. 219
Wednesday, November 13, 1985

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

FEDERAL HOME LOAN BANK BOARD

12 CFR Parts 561 and 563

[No. 85-959]

Preferred Stock as Regulatory Net Worth

Dated: October 25, 1985.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule.

SUMMARY: The Federal Home Loan Bank Board ("Board"), as operating head of the Federal Savings and Loan Insurance Corporation ("FSLIC" or "Corporation"), is amending its regulations concerning the use of non-permanent preferred stock as regulatory net worth by federally chartered associations and associations whose accounts are insured by the FSLIC. First, the amendments allow preferred stock that is redeemable at the option of the issuer to be included as regulatory net worth only if the security form of the preferred stock has been approved by the FSLIC prior to issuance of the security and the form of the security states that no redemption may be made if, after giving effect to such redemption, the insured institution would fail to meet its regulatory net-worth requirement. Second, the amendments allow mandatorily redeemable preferred stock to be included as regulatory net worth only if an application to include such preferred stock has been filed with an approved by the FSLIC. In addition, the amendments require that mandatorily redeemable preferred stock be subject to an amortization schedule which would reduce the amount of such preferred stock that may be included as regulatory net worth based on the time remaining to required redemption. Finally, the amendments explicitly prohibit any insured institution from including as regulatory net worth any capital instrument or security issued by the insured institution if such capital instrument or security is owned by a service corporation or other subsidiary controlled by the issuing insured institution. The amendments are intended to provide net-worth treatment for non-permanent stock consistent with that allowed subordinated debentures, to discourage the overstating of net worth and to encourage institutions to raise capital outside of the thrift industry.

EFFECTIVE DATE: December 13, 1985.

FOR FURTHER INFORMATION CONTACT: Gregory B. Smith, Senior Corporate Attorney, Corporate and Securities Division, Office of General Counsel, (202) 377-6454, or Francis M. Passarelli, Acting Director, Office of Examinations and Supervision, (202) 377-6366, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: By Resolution No. 85-505, dated June 21, 1985 (50 FR 29985; July 23, 1985), the Board proposed revisions to its regulations concerning the use of non-permanent preferred stock as regulatory net worth. In that proposal the Board set forth certain criteria under which mandatorily redeemable preferred stock and preferred stock redeemable at the option of the issuer may be included in an institution's regulatory net worth and clarified the ineligibility for inclusion in net worth of (1) preferred stock redeemable at the option of the holder and (2) treasury shares of permanent preferred stock and of other types of equity securities. The Board also noted in that proposal that the proposal was consistent with the limitations the Board recently imposed by Resolution No. 85-292, dated April 18, 1985 (50 FR 20550; May 17, 1985) on the net-worth treatment of subordinated debt since such debt was not equivalent to permanent capital stock and retained earnings. After considering the public comments, the Board has decided to promulgate the amendments noted hereinafter substantially as proposed, with some technical revisions made for clarification.

Summary and Discussion of Comments Received on the Proposal

The Board received seven public comments in response to its proposal. Four of the comments were received from savings and loan associations and three were from trade associations. Six commenters generally endorsed the proposal, but all of them suggested some changes or adopted the suggestions of other commenters. Only one commenter objected to the proposal as a whole.

Three commenters suggested revisions to the seven-year amortization schedule in the proposal. One suggested a five-year schedule and another suggested that amortization of the amount of the mandatorily redeemable preferred stock includable in net worth not begin until after the third year. A third commenter suggested that the seven-year amortization schedule should be replaced with a provision for the granting of an individualized amortization schedule based on the business plan submitted by each insured institution. After further consideration of this issue, the Board believes that the proposed seven-year amortization schedule is appropriate because it would be consistent with the seven-year amortization method used for subordinated debt and because it provides for a more gradual reduction of the issuer's regulatory net worth, thus giving the issuer more time either to replace the regulatory capital or adjust the amount of its liabilities to compensate for the reduction in its regulatory net worth. With regard to the use of individualized amortization schedules, the Board notes that the waiver provision in the proposed § 563.7-5(d) provides sufficient flexibility for extreme cases regarding the applicable amortization schedule while at the same time the seven-year amortization provision establishes the Board's strong preference for the seven-year method.

One commenter expressed concern that the amount of time taken for regulatory approval of mandatorily redeemable preferred stock under proposed § 563.7-5 might hamper the efficient use of such capital instruments by savings institutions. In that regard the Board notes that only the approval under § 563.1, which pertains to the form of certificate, need be obtained before issuance and that the more comprehensive approval under § 563.7-5 only need be obtained before inclusion in net worth. Thus, those institutions that may wish to issue mandatorily redeemable preferred stock immediately may request the two types of approval separately. Moreover, the proposal contained a provision that would

delegate authority to grant approval under § 563.7–5 to the Board's Office of Examinations and Supervision with the concurrence of the General Counsel. However, the Board has decided that the proposal can be refined to further expedite the approval process. The proposal contained three other related provisions that could benefit from delegations of authority. Proposed § 563.7–5(d) provides that the Corporation may waive certain provisions in (d) pertaining to requirements as to securities, § 563.7–5(f) provides that the Corporation may impose additional requirements or conditions in connection with approving the application, and proposed § 563.7–5(g) provides that the Corporation may extend an offering period for good cause upon written request by the institution. The Board believes that the inclusion of mandatorily redeemable preferred stock in net worth could be further expedited by expanding the delegation of authority in the regulation to also cover those three provisions. Moreover, the Board believes that the approvals required under § 563.1 prior to issuance of the mandatorily redeemable preferred stock form and for the form for preferred stock redeemable at the option of the issuer can also be expedited by delegating approval authority to the Board's General Counsel, or his designee. Therefore, the Board has made appropriate revisions to its proposal in the final rule being adopted today.

One commenter suggested that the eligibility criteria in proposed § 563.7–5 (b)(2)(iv) and (b)(3) are inappropriate or vague. That commenter suggests that the test regarding income available for redemption is inappropriate since that is more appropriately a question for the marketplace. The clarity of the transfer of risk provisions in proposed § 563.7–5 also was questioned by that commenter. Both provisions are identical to provisions in the the Board's analogous subordinated debt regulation § 563.8–1. It is the Board's view that since the purposes of § 563.8–1 and proposed § 563.7–5 are substantially identical, that, therefore, their provisions should be consistent. Moreover, the Board believes that by applying the test concerning income available for redemption the Board is better able to evaluate the impact of the issuance of such securities on the issuing institution, and secondarily, the credibility and, therefore, marketability of securities issued by all insured institutions will be enhanced. Further, the Board believes that the provision regarding the transfer of risk is not vague since it clearly states the principle that the issuance of the stock should transfer the risk from the Corporation to entities that are not insured institutions. For example, "collateralized" preferred stock would not result in such a transfer of risk. However, the Board does not believe that it is feasible to specify in advance all the particular situations that could be affected by this provision, and has concluded that the statement in the rule concerning transfer of risk sets forth the Board's position with appropriate clarity. The Board also notes in this regard that direct purchases of preferred stock of an insured institution by another insured institution are subject to the Board's direct investment rule at 12 CFR 563.9–8.

Another commenter objected to the proposal's requirement that the mandatorily redeemable preferred stock form contain a disclosure statement that no redemption may be made if the issuing institution fails to meet its net-worth requirement on the grounds that such a disclosure would adversely affect the marketability of the stock. The Board has concluded that the purchaser of such stock should be informed of such a significant limitation on redemption so that there can be no question regarding the notice received by a purchaser of such limitation. Moreover, failure to provide such a disclosure could significantly harm the credibility and, therefore, long run marketability of all capital raising techniques used by insured institutions.

In its proposal the Board requested comments on the proposed exclusion from net worth of all capital instruments and securities issued by an insured institution to its service corporations or other subsidiaries. The Board specifically requested comments on the following issues:

(1) For purposes of this proposal, what percentage of ownership or other tests should be used to determine when an insured institution is in control of a service corporation or other subsidiary?

(2) If the Board were to determine that less than fifty-percent ownership constituted control, should the percentage of a capital instrument or security issued by the insured institution that is excluded from the insured institution's regulatory net worth be based on the insured institution's percentage of ownership of the service corporation or other subsidiary?

(3) Should the proposed prohibition be expanded to include not only service corporations and other subsidiaries but any entity in which the insured institution has an equity investment?

In terms of the service corporation/subsidiary control test, one commenter suggested a 25 percent ownership test, one commenter suggested a 75 percent ownership test and one commenter suggested a pro rata test which would establish an ownership benchmark in each case based on the total number of investors (e.g., 4 investors: 25 percent; 100 investors: 1 percent). After considering the various alternatives, the Board has decided that a 10 percent test, consistent with that contained in the definition in § 561.28 of the term "controlling person" and as used throughout the FSLIC's regulations, would be an appropriate test of control. The Board believes that such a 10 percent test in the context of the proposed amendments to the net-worth definition, § 561.13, is an accurate benchmark above which the proposed net-worth exclusion provision should be triggered in order to prevent an overstatement of net worth under the Board's regulatory reporting procedures.

The Board also requested comments regarding whether the controlled service corporation/subsidiary should be required to exclude from net worth the total amount of the securities held by the service corporation/subsidiary or only its pro rata share based on the amount of its investment in that entity. Only three commenters addressed the issue and they suggested a pro rata exclusion. The Board has seriously considered the pro rata method, but has determined that it would be more appropriate to totally exclude the securities held by the controlled corporation/subsidiary in order to discourage overstatement of net worth and in order to encourage the raising of capital from outside of the thrift industry.

The last issue on which the Board requested comments was whether the net-worth exclusion should apply to securities issued to any entity, including partnerships and trusts, controlled by the insured institution and not just service corporations and subsidiaries. Only one commenter addressed this issue and he opposed the concept. After considering the issue, however, the Board has decided that the reasons supporting the exclusion from net worth of securities issued to service corporations and subsidiaries equally apply to all entities in which the institution has a controlling ownership interest. Therefore, the Board is applying the 10 per cent test, with appropriate modications for entities without voting stock (*e.g.* partnerships and trusts), to all entities.

The Final Rule

The current regulation, at § 561.13, permits permanent preferred stock to be included as regulatory net worth without limitation, which is consistent with the accounting treatment permitted under generally accepted accounting principles ("GAAP"). The Board has not made any changes by this amendment to the treatment of permanent preferred stock except to clarify in the text of the regulation that treasury shares of permanent preferred stock (and other types of equity securities) are not includable as net worth, which is consistent with prior interpretations and policy of the Board. Similarly, these revisions will not alter the current regulation's prohibition of the inclusion of preferred stock which is redeemable at the option of the holder as regulatory net worth, nor do the amendments alter the Board's view that preferred stock that is collateralized would not qualify as regulatory net worth.

The treatment of preferred stock that is redeemable at the option of the issuer and preferred stock that is required to be redeemed by the issuer have been revised by this amendment. First, the amendment specifies that the security form of preferred stock that is redeemable at the option of the issuer must be approved pursuant to 12 CFR 563.1, which requires that all security forms, including mandatorily redeemable preferred stock, be approved by the Corporation prior to their issuance. As noted in the comment summary section, the Board is amending § 563.1 to delegate such approval authority to the Board's General Counsel, or his designee. In addition, the security form for preferred stock that is redeemable at the option of the issuer will be required by § 561.13 to include a statement that no redemption may be made if, after giving effect to such redemption, the issuing insured institution would fail to meet its net-worth requirement under 12 CFR 563.13. The Board believes that the revision to 561.13 concerning the form of preferred-stock securities that are redeemable at the option of the issuer would ensure that no redemptions are made in violation of § 561.13 and that the investing public is aware of the regulatory restrictions on the redemption of the preferred stock.

The second revision to § 561.13 made by the Board will change the net-worth treatment of mandatorily redeemable preferred stock. The Board has concluded that mandatorily redeemable preferred stock, in terms of the degree of protection it affords the FSLIC, is substantially similar to other non-permanent capital instruments with a fixed maturity or redemption date. For that reason, written approval by the Board will be required before including mandatorily redeemable preferred stock as regulatory net worth, and such preferred stock will be subject to an amortization schedule which reduces the amount of the outstanding preferred stock that can be included as net worth based on the time remaining to required redemption. The Board is of the view that this treatment will appropriately recognize that preferred stock with mandatory redemption features does not provide the FSLIC with the same degree of protection as permanent capital stock, and will ensure that all non-permanent capital instruments with a fixed maturity or redemption date are treated consistently.

The Board is also adopting a new § 563.7–5 to set forth the criteria for review of applications for approval of mandatorily redeemable preferred stock as regulatory net worth. The provisions of proposed § 563.7–5 are substantially similar to those contained in 12 CFR § 563.8–1 and are intended to provide a basis for the Board's review of the financial condition of the issuing institution and the terms and conditions of the mandatorily redeemable preferred stock, to ensure that inclusion of the preferred stock as regulatory net worth would result in a decrease in risk to the FSLIC. The FSLIC's approval of the form of certificate of mandatorily redeemable preferred stock must be obtained before issuance, pursuant to § 563.1, and before inclusion in net worth, pursuant to new § 563.7–5. However, as noted in the comment section, in order to expedite that approval process the Board is delegating approval authority under § 563.1 to the General Counsel, or his designee, and delegating approval authority under § 563.7–5 to the Office of Examinations and Supervision with the concurrence of the General Counsel or their designees.

The final revision that the Board is making to § 561.13 provides that any capital instrument or security issued by an insured institution that is held by a service corporation or other subsidiary directly or indirectly controlled by an insured institution must be excluded from the issuing insured institution's regulatory net worth in reports filed with the Board. This revision is intended to formalize the Board's current policy concerning the treatment of capital instruments or securities of an insured institution that qualify as regulatory net worth that are held by a service corporation or other subsidiary that is controlled by the insured institution. The Board notes that under GAAP, insured institutions would be required to report their holdings in majority-owned subsidiaries on a consolidated basis, which would result in any equity securities of the parent institution held by the subsidiary being netted against the parent institution's equity. Under the Board's regulatory reporting procedures, however, the parent institution reports its investment in its service corporation by the "equity method of accounting," which could result in an overstatement of an insured institution's net worth if the service corporation or other subsidiary has invested in capital instruments or securities issued by the parent insured institution. It has always been the Board's position that the regulatory reporting procedures utilized by insured institutions should not be employed to overstate an insured institution's regulatory net worth, and the revision will explicitly prohibit such a result by disallowing net-worth treatment for capital securities of the parent held by the subsidiary.

The proposal did not define what percentage of ownership of a service corporation or other subsidiary would constitute control for purposes of determining whether capital instruments or securities held by a service corporation or other subsidiary of the insured institution should be excluded from the insured institution's regulatory net worth. Further, the proposal requested comments on that issue and on whether the Board should allow net-worth treatment by the parent of capital securities held by other entities such as partnerships or trusts that are controlled by the insured institution. As noted in the comment summary section, the Board has decided to establish a 10 percent test similar to that currently employed in § 561.28 defining controlling persons. The Board also has determined to apply that test to all forms of entities (*e.g.*, corporations, partnerships, trusts), with an appropriate modification for non-corporate entities that would apply the ten percent benchmark to the amount of that entity's capital directly or indirectly attributable to the insured institution. Finally, for the reasons noted in the comment summary section, the Board has also determined to exclude from regulatory net worth all of the securities issued to such a controlled entity.

The Board notes that pursuant to this rulemaking proceeding, it could adopt in a final rule new net-worth requirements that would be applied to all non-permanent preferred stock, both prospective and outstanding issuances. The Board, however, does not believe

that it would be appropriate to impose these restrictions on non-permanent preferred stock which was issued by insured institutions prior to July 23, 1985, the publication date of the proposal in the **Federal Register**. Thus, the final rule specifically excludes from coverage by the rule all non-permanent preferred stock which was issued in conformity with § 561.13 prior to that date.

Final Regulatory Flexibility Analysis

Pursuant to section 3 of the Regulatory Flexibility Act, Pub. L. No. 96–354, 94 Stat. 1164 (1980), the Board is providing the following regulatory flexibility analysis.

1. *Reasons, objectives and legal basis underlying the rule.* These elements are incorporated above in the supplementary information regarding the rule.

2. *Small entities to which the rule will apply.* The rule would apply to institutions whose accounts are insured by the FSLIC.

3. *Impact of the rule on small institutions.* The rule would restrict the use of non-permanent preferred stock as regulatory net worth by all insured institutions.

4. *Overlapping or conflicting federal rules.* There are no known federal rules that duplicate, overlap, or conflict with this rule.

5. *Alternatives to the rules.* There are no alternatives that would be less burdensome than the rule in addressing the concerns expressed in the supplementary information set forth above.

Lists of Subjects in 12 CFR Parts 561 and 563

Insurance of accounts, Savings and loan associations.

Accordingly, the Board hereby amends Parts 561 and 563 of Subchapter D, Chapter V of Title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER D—FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

PART 561—DEFINITIONS

1.The authority citations for 12 CFR Parts 561 and 563 continue to read:

Authority: Sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1437); Secs. 1 and 5, 48 Stat. 128 and 132, as amended (12 U.S.C. 1462 and 1464); Sec. 409, 94 Stat. 160, Sec. 5A, 47 Stat. 736, as amended (12 U.S.C. 1464); Secs. 401, 402, 403, 405, 406, 407, 48 Stat. 1255, 1256, 1257, 1259, 1260, as amended (12 U.S.C. 1724, 1725, 1726, 1729, 1730); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–1948 Comp., p. 1071; sec. 4, 80 Stat. 824, as amended (12 U.S.C. 1425a).

2. Amend § 561.13 by revising paragraph (a); redesignating paragraph (d) as paragraph (f); and adding new paragraphs (d) and (e); as follows:

§ 561.13 Regulatory net worth.

(a) The term "regulatory net worth" means the sum of all reserve accounts (except specific or valuation reserves), retained earnings, permanent common stock, permanent preferred stock, non-permanent preferred stock issued prior to July 23, 1985, mutual capital certificates (issued pursuant to § 563.7–4 of this subchapter), securities which constitute permanent equity capital in accordance with generally accepted accounting principles (if approved by the Corporation), appraised equity capital (as defined in § 563.13(c) of this subchapter), and any other nonwithdrawable accounts of an insured institution (excluding any treasury shares held by the insured institution): *Provided,* that for any nonpermanent instrument qualifying as regulatory net worth under this paragraph, either (1) the remaining period to maturity or required redemption (or time of any required sinking fund or other prepayment or reserve allocation, with respect to the amount of such prepayment or reserve) is not less than one year, or (2) the redemption or prepayment is only at the option of the issuing insured institution and such payments would not cause the insured institution to fail or continue to fail to meet its net-worth requirement under § 563.13 of this subchapter; and *Provided further,* that capital stock may be included as net worth without limitation if it would otherwise qualify but for either (i) a provision permitting redemption, in the event of a merger, consolidation, or reorganization approved by the Corporation where the issuing institution is not the survivor, or (ii) a provision permitting a redemption where the funds for redemption are raised by the issuance of permanent stock.

* * * * *

(d) The term "regulatory net worth" also includes:

(1) Preferred stock that is redeemable at the option of the issuer (1) which was issued prior to July 23, 1985, or (ii) which was issued after July 23, 1985: *Provided,* that the form of the security was approved prior to issuance pursuant to § 563.1 of this subchapter and states that no redemption may be made by the issuing insured institution if, after giving effect to such redemption, the insured institution would fail to meet its net-worth requirement under § 563.13 of this subchapter;

(2) Mandatorily redeemable preferred stock which (i) was issued prior to July 23, 1985, or (ii) was issued pursuant to § 563.7–5 of this subchapter, after July 23, 1985, was approved as to its form prior to issuance pursuant to § 563.1 of this subchapter, and was approved in writing by the Corporation for inclusion as net worth, before or after its issuance, pursuant to § 563.7–5: *Provided,* that unless otherwise approved by the Corporation in writing, mandatorily redeemable preferred stock issued after July 23, 1985, may be included as net worth only in accordance with the schedule set forth in paragraph (c)(1) of this section and consistent with the provisions of paragraphs (c) (2) and (3) of this section.

(e) Notwithstanding paragraphs (a), (b), (c) and (d) of this section, the term "regulatory net worth" does not include any capital instrument or security which may be included as regulatory net worth pursuant to any of those paragraphs if such capital instrument or security is held by a service corporation or other subsidiary, regardless of the organizational form of that entity, in which the insured institution directly or indirectly, (i) owns, controls, or holds with power to vote, or holds proxies representing, ten per cent or more of the voting shares or rights, or (ii) invested or contributed more than ten per cent of such entity's capital, unless net-worth inclusion is specifically approved by the Corporation in writing.

PART 563—OPERATIONS

§ 563.1 [Amended]

3. Amend § 563.1(a) by inserting between the third and fourth sentences thereof, the following: "Notwithstanding any other delegation of the authority granted under this paragraph, the General Counsel or his designee, are delegated exclusive authority to exercise the Corporation's approval authority under this paragraph with respect to preferred stock security forms and amendments thereto for mandatorily redeemable preferred stock and preferred stock redeemable at the option of the issuer."

4. Add new § 563.7–5 as follows:

§ 563.7–5 Mandatorily redeemable preferred stock.

(a) *General.* No insured institution shall issue mandatorily redeemable preferred stock includable in regulatory net worth pursuant to this section or amend the terms of such preferred stock unless it has obtained the written approval of the Corporation. Approval of the issuance under this section, in

order to qualify as regulatory net worth under § 561.13 of this subchapter, may be obtained either before or after the preferred stock is issued, but no approval shall be granted unless the issuance of the preferred stock and the form and manner of filing of the application are in accordance with the provisions of this section.

(b) *Eligibility requirements.* In determining whether the Corporation will process an application by an insured institution for approval of the issuance of mandatorily redeemable preferred stock includable in regulatory net worth pursuant to this section, the Corporation will consider the following factors:

(1) Whether the issuance of such preferred stock by the applicant is authorized by applicable law and regulation and is not inconsistent with any provision of the applicant's charter, constitution, or bylaws;

(2) Whether, in the opinion of the Corporation, the overall policies, condition, and operation of the applicant do not afford a basis for supervisory objection to the application. Bases for supervisory objection may include the following:

(i) Net worth, without regard to the amount of any mandatorily redeemable preferred stock to be included in net worth, does not meet the requirements of § 563.13;

(ii) Scheduled items exceed 2.5 percent of specified assets;

(iii) Losses have not been offset by specific reserves to the extent required pursuant to § 563.17–2 of this part;

(iv) Actual and anticipated income from operations, after distribution of earnings to the holders of savings accounts, payment of dividends on outstanding equity securities and payment of interest on borrowings but before income taxes, is not demonstrably sufficient for payment of dividends and redemption price, discount, and related expenses of the proposed issue; and

(3) Whether the issuance of such securities by the applicant in the transaction and any related transactions will result in a transfer of risk from the Corporation to parties other than insured institutions.

(c) *Application form; supporting information.* An application for approval of the issuance of mandatorily redeemable preferred stock by an insured institution pursuant to this section shall be in the form prescribed by the Corporation or, if no such form has been promulgated, may be in the form prescribed by the Corporation for the issuance of subordinated debentures, in which case all references therein to "subordinated debt," "debt service," or "debt discount" shall be changed to, respectively, "mandatorily redeemable preferred stock," "debt or redemption service" and "redemption discount" and all citations therein to § 563.8–1 changed to corresponding provisions, if any, of § 563.7–5. Such application and instructions may be obtained from the Supervisory Agent. Information and exhibits shall be furnished in support of the application in accordance with such instructions, setting forth all of the terms and provisions relating to the proposed issue and showing that all of the requirements of this section have been or will be met.

(d) *Requirements as to securities.* Mandatorily redeemable preferred stock issued pursuant to this section shall meet all of the following requirements unless one or more of such requirements, not including (1)(i) of this paragraph (d) which is not eligible for waiver, are waived by the Corporation.

(1) *Form of certificate.* Each certificate evidencing mandatorily redeemable preferred stock issued by an insured institution pursuant to this section shall:

(i) Bear on its face, in bold-face type, the following legend: "This security is not a savings account or deposit and it is not insured by the Federal Savings and Loan Insurance Corporation";

(ii) Clearly state that the security is unsecured and is not eligible as collateral for any loan by the issuing institution; and

(iii) State or refer to a document stating that no redemption, other than scheduled redemptions, may be made by the issuer if after giving effect to such redemption the institution would fail to meet the net-worth requirements of § 563.13.

(2) *Limitation as to term.* No mandatorily redeemable preferred stock issued by an insured institution pursuant to this section shall have an original period to required redemption of less than seven years. During the first six years that such a security is outstanding, the total of all required purchase-fund payments, required reserve allocations and required redemptions with respect to the portion of such six years that have elapsed shall at no time exceed the original redemption price thereof multiplied by a fraction the numerator of which is the number of years that have elapsed since the issuance of the security and the denominator of which is the number of years covered by the original period to required redemption.

(e) *Filing of application.* The application for approval of the issuance of mandatorily redeemable preferred stock under this section shall be filed with the Corporation by transmitting the original and two copies of the application and all supporting documents to the Supervisory Agent. As used in this section, the term "Supervisory Agency" means the President of the Federal Home Loan Bank of the district in which the applicant is located or any other officer or employee of such Bank designated by the Board as agent of the Corporation, as provided by § 501.10 or § 501.11 of this chapter.

(f) *Additional requirements.* The Corporation may impose on the applicant such requirements or conditions with regard to the securities or the offering or issuance thereof as it may deem necessary or desirable for the protection of purchasers, the applicant, or the Corporation.

(g) *Limitation on offering period.* Following the date of approval of the application by the Corporation, the institution shall have an offering period of not more than one year in which to complete the sale of the mandatorily redeemable preferred stock issued pursuant to this section. The Corporation may in its discretion extend such offering period if a written request showing good cause for such extension is filed with it not later than 30 days before the expiration of such offering period or any previous extension thereof.

(h) *Reports.* Within 30 days after completion of the sale of the mandatorily redeemable preferred stock issued pursuant to prior approval under this section, the institution shall transmit a written report to the Supervisory Agent stating the number of purchasers, the total dollar amount of securities sold, and the amount of net proceeds received by the institution.

(i) *Delegations.* The Director of the Office of District Banks, or his designee, with the concurrence of the Director of the Office of Examinations and Supervision, or his designee, and the General Counsel, or his designee, are authorized to (1) approve any mandatorily redeemable preferred stock applications filed pursuant to this section if they are in compliance with regulatory requirements or waivers thereof, and (2) except for denial of the application, otherwise act on the Corporation's behalf under any provision of this section, unless they are of the opinion that the application involves policy considerations which warrant formal consideration by the Corporation.

By the Federal Home Loan Bank Board.
Jeff Sconyers,
Secretary.
[FR Doc. 85-26961 Filed 11-12-85; 8:45 am]
BILLING CODE 6720-01-M

12 CFR Part 591

[No. 85-958]

Preemption of State Due-on-Sale Laws; Imposition of Prepayment Penalties

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule.

SUMMARY: The Federal Home Loan Bank Board ("Board") is revising its regulation prohibiting lenders, including their assignees and transferees, from imposing prepayment penalties for or in connection with acceleration of loans on the security of borrower-occupied homes by the exercise of due-on-sale clauses. The amendments are intended to clarify the existing consumer-protection provision and to add a new provision to the regulations. As revised, the regulations will prohibit prepayment penalties with respect to loans on the security of borrower-occupied homes if a lender (1) exercises a due-on-sale clause by written notice, (2) commences a foreclosure proceeding to enforce a due-on-sale clause or to seek payment in full as a result of invoking such a clause, or (3) fails to approve within 30 days the completed credit application of a qualified transferee to assume the loan in accordance with its terms, and thereafter, within 120 days of the lender's receipt of such application, the borrower transfers the home to that transferee and prepays the loan in full. The new consumer protection afforded by this revision will apply to loans outstanding or originated on or after its effective date.

EFFECTIVE DATE: December 13, 1985.

FOR FURTHER INFORMATION CONTACT: Joseph Longino, Special Counsel, Regulations and Legislation Division, Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, D.C. 20552; (202) 377-6446.

SUPPLEMENTARY INFORMATION: A Board regulation currently prohibits lenders, as well as their assignees and transferees, from imposing a prepayment penalty for or in connection with the exercise of a due-on-sale clause to accelerate a loan on a home occupied or to be occupied by the borrower. 12 CFR 591.5(b)(2). This prohibition is restricted to situations in which the lender has actually "called" or accelerated the loan by requesting payment in full. Under the regulation, borrowers who prepay loans in anticipation of due-on-sale acceleration—even when lenders have communicated this intent—may be charged prepayment penalties. *See, e.g.*, Office of General Counsel ("OGC") Opinion Letter (Apr. 23, 1984) (construing 12 CFR 591.5(b)(2) (1984)); OGC Opinion Letter (Feb. 26, 1979) (construing predecessor provision applicable to Federal associations, 12 CFR 545.6-11(g)(2) 1979)). This situation appears to arise most commonly when a borrower asks a lender whether the existing loan may be assumed by a prospective purchaser of the home. On the other hand, borrowers who structure the sales of their homes in a manner that compels lenders to enforce due-on-sale clauses may not be charged prepayment penalties.

On August 2, 1984, the Board proposed to revise its regulation in response to congressional concern for consumer protection and the unfairness of permitting lenders which have not formally called a loan to achieve the same result by giving notice of an intent to do so and then charging a penalty upon prepayment. With respect to loans on the security of borrower-occupied homes, the proposed revision would have prohibited the collection of a prepayment penalty if a lender (1) exercised a due-on-sale clause by written notice, (2) commenced a foreclosure proceeding to enforce a due-on-sale clause or to seek payment in full as a result of invoking such a clause, or (3) failed to consent within a reasonable time to the written request of a qualified purchaser to assume the loan in accordance with its terms, and thereafter the borrower sold or transferred the home to that purchaser and prepaid the loan in full. Board Res. No. 84-401, 49 FR 32081 (Aug. 10, 1984).

The Board initially provided for a 30-day comment period ending on September 10, 1984, in order to expedite the rulemaking process. On November 21, 1984, the Board extended the comment period for 60 days, through January 28, 1985, to permit a more thorough evaluation of the issues being raised and modified the proposed effective date of any final rule to be 30 days after publication in the **Federal Register**. Board Res. No. 84-667, 49 FR 46911 (Nov. 29, 1984).

As the Board noted in proposing the revision to its rule, lenders have increasingly imposed penalties in connection with the prepayment of loans in anticipation of loan acceleration. While lenders for years commonly have had the contractual right to impose penalties upon the prepayment of loans, in the past many have waived that right if market interest rates at the time of prepayment permitted them to reloan the money prepaid at an equivalent or higher interest rate. In the wake of the impact of the interest-rate crisis of 1981-82 upon the financial condition of many institutional lenders, however, such lenders have been much less willing to waive this right, even when the interest rate on the loan prepaid is below market interest rates. As a result, borrower complaints to the Board and to Congress have increased. The final rule is the Board's means of enabling borrowers to insulate themselves from prepayment penalties on home loans that lenders will not permit to be assumed because of market conditions.

The Board received letters from a total of 74 commenters, including 8 individuals, 49 institutional lenders, 15 trade associations and law firms representing institutional lenders, realtors, or consumers, the Comptroller of the Currency, which charters, regulates, and supervises national banks, and the Committee on Banking, Housing, and Urban Affairs of the United States Senate. Most letters were submitted as comments on the proposal, but the Board treated some letters as comments even though not submitted as such in order to consider fully public opinion on this issue. The Board also considered late-filed and late-received letters. Most institutional lenders and the trade associations and law firms representing them oppose the proposed revision, while other commenters generally support the proposal. Both supporters and opponents suggest various substantive and technical amendments to the proposal. A few commenters suggest alternatives to the proposal. Commenters also raise certain procedural concerns. These comments are discussed below, as are the modifications to the proposal that the Board has incorporated in the final rule.

In addition to expressing concerns that were addressed in the preamble to the proposed rule (congressional concern for consumer protection and fairness to borrowers), the comments raise other substantive issues, including the Board's statutory authority to promulgate the rule, the completeness of the rule's effectuation of congressional intent, the contractual equity of the rule to lenders, and the economic impact of the rule.

Statutory authority and congressional intent. Some commenters argue that the Board lacks statutory authority for its

proposed regulation. They opine that neither section 341 of the Garn-St Germain Depository Institutions Act of 1982 ("Act"), 12 U.S.C. 1701j–3, nor its legislative history expressly indicates that Congress intended the Board to adopt a prepayment-penalty regulation of general applicability. Such commenters reject the suggestion that such a regulation falls within the Board's authority to adopt additional consumer protections that Congress "has not foreseen," arguing that Congress must have been aware of the use of prepayment penalties when it exhaustively studied the entire due-on-sale issue. Further, they argue that such a regulation, being restrictive, runs counter to the general directive of section 341(b)(2) that due-on-sale clauses shall be "exclusively governed by the terms of the loan contract." Another commenter suggests that section 341(d)((9) of the Act gave the Board authority to address only transfers involving the exercise of due-on-sale clauses and did not extend to a lender's refusal to permit an assumption. Finally, one commenter argues that prepayment penalties are a proper subject for state regulation and that state consumer protections in this area are adequate.

The Board disagrees with the views expressed by the commenters in this area and believes that it has clear authority to promulgate the proposed rule under section 341. Section 341(e)(1) authorizes the Board "to issue rules and regulations and to publish interpretations governing the implementation" of section 341. Congress unambiguously intended this rulemaking authority to extend to the consumer protections set forth in section 341(d). As described in the Senate Report, paragraph (9) of section 341(d) "permits the . . . Board to use its rulemaking authority to provide additional consumer protections for circumstances where the enforcement of due-on-sale would be inequitable, which the Committee has not foreseen." S. Rep. No. 536, 97th Cong., 2d Sess. 58–59 (1982). The rule is such a consumer protection. While the rule is phrased in terms of the imposition of prepayment penalties, it effectively imposes a limitation on the exercise of due-on-sale clauses "where the enforcement of due-on-sale would be inequitable." *See, e.g.*, Board Res. No. 76–100, 41 FR 6283, 6285–86 (Feb. 12, 1976) (characterizing a proposed prepayment-penalty prohibition applicable to Federal associations as a limitation on their contractual right to exercise due-on-sale clauses). If the lender wishes to impose a prepayment penalty, it may not enforce a due-on-sale clause because the Board has determined that enforcement of a due-on-sale clause simultaneously with the imposition of a prepayment penalty is inequitable.

In light of the Board's rulemaking authority, the absence of a statutory provision or legislative history discussing the use of prepayment penalties does not suggest that the Board lacks statutory authority to adopt the rule. The statute and its legislative history specifically anticipate that the Board will adopt consumer protections "not foreseen" by Congress and therefore not mentioned by Congress in the course of adopting the legislation. A commenter's suggestion at the other extreme that the Board must somehow affirmatively demonstrate that Congress did not foresee the problems created by prepayment penalties is equally unavailing. The Board obviously need not prove a negative. Congress gave the Board broad discretion to determine whether additional consumer protections in this area were warranted, granting the Board clear authority to adopt this regulation.

In addition, the fact that section 341 generally expands the utility of due-on-sale clauses and provides as a general matter that due-on-sale clauses be "exclusively governed by the terms of the loan contract," 12 U.S.C. 1701j–3(b)(2), does not detract from the scope of the rulemaking authority Congress gave the Board. While Congress liberalized the use of due-on-sale clauses overall, it expressly recognized the need to prohibit the use of these clauses in certain situations in order to protect consumers and gave the Board the authority to determine under what circumstances such protections were needed.

The Board also disagrees with the suggestion that it is empowered under section 341(d)(9) to address only the formal exercise of due-on-sale clauses. The other situation addressed by the rule—failure to approve a completed credit application for an assumption of the loan by a transferee followed by transfer of the property to that transferee and prepayment of the loan in full—is functionally equivalent to formal enforcement of a due-on-sale clause from the perspective of the consumer and results in the same unfairness to the consumer. The authority to provide consumer protection in this situation is clearly encompassed in section 341(d), as well as in the general grant of rulemaking authority to the Board in section 341(e)(1). Finally, based upon the complaints which the Board and Congress have received, the Board has determined that state regulation has not provided consumers sufficient protection in this area and that federal regulatory action is appropriate.

As a separate matter, some commenters request that the Board clarify the relationship between any final rule and the ability of lenders, including Federal associations, to charge prepayment penalties under circumstances other than those addressed in the proposal. One commenter urges the Board to preempt all state laws limiting the enforcement of prepayment-penalty clauses. Another commenter requests the Board to clarify that the rule would not prohibit lenders from rewriting loans at higher interest rates. Several commenters suggest that congressional intent would be better served if the rule permitted a lender to impose a penalty upon the prepayment of any loan that the lender is willing to rewrite at a submarket rate of interest.

The Board does not consider it appropriate or necessary to preempt all state laws limiting the enforcement of prepayment-penalty clauses. The Board has previously noted that the ability to impose a prepayment penalty is not essential to the effective use of due-on-sale clauses for the purpose of raising portfolio yields to current market interest rates. Board Res. No. 83–242, 48 FR 21554, 21560 (May 13, 1983). Federal associations may include prepayment-penalty clauses in any loan they make and, except for limitations imposed by Board regulations, enforce such clauses according to their terms, state law—including equitable principles—notwithstanding. *See* OGC Opinion Letter (Oct. 9, 1985) (construing 12 CFR 545.2, 545.34(c), 591.5(b)(2) (1985)).[1]

[1] The full text of the October 9, 1985, opinion letter, signed by Norman H. Raiden, General Counsel to the Board, follows:

In your January 31, 1984, letter you request the opinion of this office on three questions concerning a Federal association's enforcement of prepayment penalty clauses in commercial real estate loans. I apologize for the delay in responding to your request. To simplify our response, I answer your questions out of order.

In your second question, you inquire whether the Federal Home Loan bank Board (Board) imposes any limitation on the ability of a Federal association to enforce a prepayment penalty clause in a commercial loan in accordance with its terms, even if the "prepayment" occurs as a result of the enforcement of some other provision of the loan contract, such as a due-on-sale clause. The answer is that the Board imposes no such limitation.

In your first and third questions, you inquire whether §§ 545.2 and 545.34(c), as amended at 49 FR 43044 (Oct. 26, 1984), of the Federal Regulations, 12 CFR 545.2, 545.34(c) (1985), authorize a Federal association to include a prepayment penalty clause in any loan it makes and to enforce such a clause in

Continued

Lenders other than Federal associations should consult applicable federal and state law. *See* 48 FR at 21560.

The Board wishes to clarify that the final rule does not prohibit lenders from rewriting loans, whether fixed- or adjustable-rate, at higher interest rates or with otherwise different terms. The Board does not agree, however, that congressional intent would be better served if the rule permitted a lender to impose a penalty upon the prepayment of any loan that the lender is willing to rewrite at a submarket rate of interest or with otherwise different terms. As is discussed more fully below, the Board takes this position because the benefit of the bargain for the lender is to have a creditworthy borrower obligated on the loan for its stated term to maturity.

Finally a few commenters are laboring under some confusion regarding the scope of section 341 and the Board's implementing regulations. These commenters variously assume that section 341 and its implementing regulations apply only to lenders in states whose laws previously restricted enforcement of due-on-sale clauses or only to institutions the accounts of which are insured by the Federal Savings and Loan Insurance Corporation ("insured institutions"), and that the term "lenders" as used in the statute and the rules does not include the assignees and transferees of the originators of loans.

These assumptions are all misconceptions of the law. Section 341 of the Act established a national policy governing the use of due-on-sale clauses by affirming the federal preemption of state due-on-sale prohibitions and restrictions as to Federal associations and by extending that preemption generally to all other lenders originating or holding real property loans, whether commercial or residential. *See, e.g.*, 12 U.S.C. 1701j–3 (b)(1), (c)(2)(C); 12 CFR 591.1(b). Section 341 was not enacted as part of the National Housing Act, which vests in the Board authority over insured institutions, but, rather, it was enacted as part of the Thrift Institutions Restructuring Act. 12 U.S.C. 1701j–3 codification note. Thus, the reach of section 341 and its implementing regulations is not confined to insured institutions. Instead, in both the statute and the rules, the term "lender" is broadly defined to include not only institutions but also natural persons, as well as a lender's assignees and transferees. 12 U.S.C. 1701j–3(a)(2); 12 CFR 591.2(g).

Contractual inequity to lenders. Lenders argue that it is inequitable for the Board to release borrowers from the only negative aspect of bargains that have greatly benefited borrowers and to penalize lenders by denying them their contractual right to recoup a small portion of their losses on below-market-rate loans. Some commenters characterize the rule as creating a "loophole" through which the transferee may insulate the borrower from a prepayment penalty by submitting an application to assume the loan. A few commenters note that lenders have already suffered losses arising from transfers "subject to" the mortgage, forcing them to call loans and forego prepayment penalties, and transfers without notice to lenders, depriving them of their ability to call below-market-rate loans. A number of commenters urge making the rule applicable only to loans originated on or after its effective date so as not to deprive lenders unfairly of their contractual rights. One commenter is concerned that lenders will be sued for reimbursement of prepayment penalties charged in the past.

The Board does not believe that the final rule is inequitable to lenders; nor does the Board believe that the operation of the rule will create a "loophole." The implicit premise of the rule is that the benefit of the bargain for the lender is to have a creditworthy borrower obligated on the loan for its stated term to maturity. *See* 49 FR 32081. In the Board's opinion, equity demands that no prepayment penalty be permitted if a lender does not wish to allow a loan to remain outstanding by approving its assumption by a qualified obligor.

As is discussed above, the Board believes the final rule to be an appropriate addition to the consumer protections set out in section 341(d) of the Act. The application of new § 591.5(b)(3) to all outstanding loans on the security of borrower-occupied homes rather than to subsequently originated loans only is consistent with the application of the other consumer protections contained in the statute and in the Board's implementing regulations, including § 591.5(b)(2), *see* 49 FR at 32082, and will afford consumers comprehensive protection against the type of inequitable enforcement of contractual provisions that Congress intended the Board to address. Thus, the Board is making the new, separate provision of the final rule applicable to loans outstanding on its effective date rather than merely to those originated on or after such date. Finally, the Board notes again that the final rule will not provide a basis for restitution of prepayment penalties imposed prior to the effective date of the rule under circumstances which the rule newly prohibits. *See id.*

Furthermore, as the Board noted in the proposal, it is not equitable for a lender that has not formally called a loan to achieve the same result by giving notice of an intent to do so and then to demand a penalty upon prepayment. *See* 49 FR at 32082. Thus, the Board does not believe that lenders have been unfairly used by borrowers who have transferred their homes "subject to" the mortgage as a means of avoiding a prepayment penalty.

The Board, however, does appreciate that some borrowers have breached their contracts by transferring their homes without notice to lenders even though due-on-sale clauses commonly provide that the security property may not be transferred without the prior written consent of the leader. Such borrowers deprive lenders of their federally protected contractual rights to call below-market-rate loans. The Board hereby requests lenders to advise it whether remedies under state law are adequate to make them whole as to such breaches. If state-law remedies are inadequate, the Board intends to consider further rulemaking to secure for lenders the full measure of protection Congress sought through its passage of section 341 of the Act.

Lenders comment that they regard the prepayment-penalty clause as a hedge against the risk of fixed-rate lending. They further maintain that the prepayment penalty enables them to recover the fixed costs of making a loan, which would otherwise be lost through early retirement of the loan. One comment also notes that a prepayment penalty compensates for lost income

---

accordance with its terms even if state law, including equitable principles which might be applied in a foreclosure action, purports to prohibit the collection of a prepayment penalty under certain circumstances.

In pertinent part, § 545.34(c) provides that "an association may impose a penalty on prepayment of a loan as provided in the loan contract." Because of the preemptive effect of § 545.2, this authority is subject only to the limitations with respect to loans secured by borrower-occupied homes found or referred to in § 545.34(c) itself (governing disclosure and the imposition of a prepayment penalty after notice of an adjustment of an adjustable-rate mortgage) and found in 12 CFR 591.5(b)(2) (1985) (prohibiting the imposition of a prepayment penalty for or in connection with due-on-sale acceleration). The ability to include a prepayment penalty clause in a loan is, of course, a prerequisite to enforcement. Thus, this office is of the opinion that a Federal association may include a prepayment penalty clause in any loan it makes and, except for limitations imposed by Board regulations, enforce such a clause according to its terms, state law—including equitable principles—notwithstanding.

I hope you find these responses to your questions helpful.

while a lender investigates reinvestment opportunities for the proceeds of repayment.

Although a prepayment penalty may serve as a hedge against the risk of fixed-rate lending, the Board notes that such a penalty is only one type of protection available to manage the asset-liability position of a lender's portfolio. Lenders arguing that prepayment penalties are necessary to recover the fixed costs of making or retiring a loan overlook their ability to recover such costs by imposing fees such as reasonable loan-origination fees, retirement fees, and assumption fees. Finally, if a lender is not able to reinvest the proceeds of a prepaid loan without significant lost income, common sense would suggest permitting an assumption of the loan.

Some lenders reason that the proposed rule is unjustified because a truth-in-lending disclosure statement conspicuously highlights for the borrower the due-on-sale clause and the prepayment-penalty clause. Such commenters view the prepayment-penalty clause as a bargained-for contractual provision and view the true benefit of the bargain as including the right of the lender to charge a prepayment penalty. They point out that prepayment-penalty clauses are not standard and that applicants may shop for a loan not having such a clause. One borrower, however, maintains that disclosure of prepayment-penalty clauses is often too late—as late as the date of consummation of the loan—to enable a borrower to object without losing a deposit. Even with adequate disclosure, a number of commenters view prepayment penalties as unfair when lenders refuse to permit assumptions or call loans.

The Board recognizes the value of truth-in-lending disclosures and the ability of applicants to shop for home loans not having prepayment-penalty clauses. The Board does not believe, however, that arguments based on disclosure and comparative shopping adequately rebut the Board's understanding of the benefit of the bargin for the lender and the consequent inequity of permitting lenders that no longer wish to retain this benefit to charge penalties upon the prepayment of loans having submarket rates of interest. Thus, the Board believes that the new protection of the final rule is a necessary complement to the consumer protections already in place.

Economic impact. Lenders argue that the proposed rule would further erode the earnings and net worth of an already fragile industry, with crippling effects for some institutions. Data presented in some of the comments purports to indicate that prepayment charges account for 12.5 percent of one institution's total annual income, that associations in Wisconsin could lose as much as $10 million annually, and that lenders in California could lose as much as $600 million annually. Lenders also express concern that loans in portfolio would be worth less when sold in the secondary market. A few lenders apparently assume that the rule would prohibit the imposition of penalties upon the prepayment of home loans under all circumstances.

Some lenders, however, support the proposed rule, reasoning that what is most important to institutions is expanding profitable services and using due-on-sale clauses to restructure portfolios. A few commenters believe that the proposed rule represents a reasonable balance of the interests of borrowers and lenders in that it probably would not result in a significant loss of income to lenders. One commenter suggests that lenders need to make short-term concessions to promote long-term economic gain for all. Commenters representing realtors support the proposed rule as a means of eliminating the use of legally and economically inefficient transfers "subject to" the mortgage.

As the Board observed in the proposal, it has no reason to believe that the economic effect of the rule upon lenders would be significant. As some commenters observe, what is most important to lenders is using due-on-sale clauses in restructure portfolios by calling below-market-rate loans and reinvesting the proceeds of loan payoffs at higher interest rates. 49 FR at 32082–83. It is this ability to restructure which section 341 of the Act sought to secure for lenders. *See* 48 FR at 21560. The Board further notes that the practical effect of the final rule is to permit a lender to charge a prepayment penalty if a loan having an above-market rate of interest is prepaid, so that lenders would be compensated for being deprived of the benefit of the bargain in this circumstance.

Finally, the Board notes that none of the information submitted that purported to quantify the adverse economic impact of the rule on lenders related specifically to the actual operation of the rule. Instead of submitting data quantifying for single institutions or for some larger set of institutions the magnitude of loss the rule would actually have caused for some recent historical period, commenters who submitted data chose instead to describe worst-case scenarios based upon the elimination of *all* prepayment penalties. The Board interprets the failure of commenters to submit persuasive data—which presumably would be in the possession of institutional lenders—as an indication that the Board is correct in its belief that the adverse economic impact of the rule upon lenders will be minimal.

A few commenters suggest that the refund of unearned interest upon loan prepayment required in Wisconsin, Wis. Stat. Ann. 138.052(2)(b) (West Supp. 1985), would expose lenders in that state to a cash refund liability on amounts previously collected on residential mortgage loans. They argue that the proposed regulation would upset a balance of charges, creating not only a loss of income but also a severe cash outflow for Wisconsin lenders.

The Board acknowledges that, because of Wisconsin law, the rule as adopted may have a more significant economic impact upon lenders in Wisconsin than in other states. State laws in other states not brought to the Board's attention may also change the impact of the rule in those states. The Board notes that lenders in such states may seek appropriate relief from state legislatures. Such an approach is more likely to result in the appropriate coordination of the provisions of federal and state law than for the Board to begin a process of creating exceptions to its rule.

Commenters also argue that the proposed rule would adversely affect borrowers because lenders would try to recoup losses on existing loans by charging more on newly originated loans, thereby forcing future borrowers to subsidize current borrowers. The effect, they argue, could be to deprive marginally qualified borrowers of a chance for homeownership. Moreover, mortgage-subsidy programs for poorer homeowners could be adversely affected in that such programs keep interest rates low by using prepayment penalties to lock in mortgage yields sufficient to repay bondholders.

The Board believes that lenders will lose little income because of the rule, so there will be little loss to pass on to future borrowers. Prepayment penalties are not standard in home loans and, in fact, are prohibited in certain loans to be sold in the secondary market. Furthermore, lost income may be recouped in ways other than by charging more on newly originated loans, just as fixed-rate loans may be hedged in ways other than by reliance on prepayment penalties. Mortgage-subsidy programs relying in part upon prepayment penalties may employ other hedging techniques.

Technical suggestions. Commenters offer various suggestions in response to the Board's specific solicitation of comments on whether lenders should be required to consent to a requested assumption within a set number of days instead of a "reasonable time." While one commenter fears that a fixed time would invite lender delay, most commenters believe that a fixed time would avoid potential abuse. Commenters generally suggest that a time period be chosen that reflects industry practice. A period of not fewer than 30 days and not more than 60 days is the most common suggestion. Commenters recommend a 30-day period based on its consistency with two different regulatory provisions: the Board's due-on-sale regulations, 12 CFR 591.4(d)(3), and the Federal Reserve Board's regulations implementing the Equal Credit Opportunity Act, 12 CFR 202.2(f), 202.9(a)(1)(i). One commenter suggests requiring the transfer to occur within 90 days as a means of avoiding a perpetual waiver (as to a particular transferee) by the lender of its right to enforce a prepayment-penalty clause. Several commenters urge the Board to clarify the meaning of the "written request" to which the lender may fail to consent.

In response to these comments, the Board has determined to provide more regulatory certainty by providing in the final rule that what insulates the borrower from a prepayment penalty is, in part, the failure of the lender to approve a "completed credit application," not its failure to consent to a "written request." The phrases "completed credit application" and "completed application for credit" are already contained in the Board's due-on-sale regulations and in the regulations implementing the Equal Credit Opportunity Act.

The term "completed application for credit" is defined in 12 CFR 202.2(f) to mean the receipt by the lender of all information regularly obtained and considered in evaluating applications for the amount and type of credit requested, including, but not limited to, credit reports, any additional information requested from the applicant, and any approvals or reports by governmental agencies or other persons that are necessary to guarantee, insure, or provide security for the credit or collateral. The Board has determined to adopt this definition for the term "completed credit application" by incorporating by reference in § 591.2(a) of its due-on-sale regulations the definition found at 12 CFR 202.2(f). The Board notes that the definition imposes on lenders the obligation to exercise reasonable diligence in obtaining information needed to complete a credit application, including a reasonable effort to notify the applicant of incompleteness which is within the power of the applicant to cure.

In addition, the Board has further modified the text of the proposed rule to provide that, after receipt of a completed credit application, the lender has 30 days to approve the application and the borrower has 120 days to transfer the home and prepay the loan in full.

Other technical suggestions include clarifying that prepayment penalties do not include the assessment of foreclosure costs, that the borrower-occupancy requirement contemplates actual occupancy or good-faith intent to occupy, that any transferee—rather than "purchasers" only—benefit from the rule, and that the term "qualified" goes to the creditworthiness of the transferee. Several commenters urge deletion of the qualification requirement. Commenters also request clarification of the ability of lenders to charge reasonable assumption fees and of the meaning of the phrase "in accordance with its terms" with respect to an agreed-upon assumption.

In response to these suggestions, the Board has modified the proposal in several ways. First, the term "transferee" is substituted for "purchaser" to ensure that a gift of title to a home will fall within the ambit of the rule. Second, the Board has used and defined in the final rule the term "qualified transferee" in a manner that clarifies that the transferee must be creditworthy under the lender's applicable underwriting standards and must occupy the home currently or in the near future. The Board notes that the introductory phrase of § 591.5(b) ("With respect to any loan on the security of a home occupied or to be occupied by the borrower,") generally requires that the loan be made to or, with the permission of the lender, assumed by the borrower-occupant and that the borrower—as distinct from the transferee—currently occupy the home. The Board rejects the suggestion that borrowers be insulated against prepayment penalties unless they present lenders with the option of permitting an assumption by a qualified transferee because such a formulation would not give lenders the choice of retaining the benefit of their bargain.

The Board takes this opportunity to clarify that the regulation does not limit or prohibit the imposition of any other fees, such as reasonable loan-assumption fees, retirement fees, or foreclosure fees, and that an assumption "in accordance with the terms of the loan" contemplates the substitution, without more, of one obligor for another, thereby releasing the prior obligor from personal liability on the loan. The rule will not compel lenders to permit assumptions, but it will prohibit them from charging penalties for the prepayment of loans whose assumption they will not permit. In assessing fees other than prepayment penalties, lenders should note that the rule regulates not only prepayment penalties but also "equivalent fees." If loan-assumption or other fees were unreasonable, they could constitute fees equivalent to prepayment penalties subject to the final rule.

Finally, one commenter questions whether the rule requires lenders to ensure that borrowers are aware of the rule and its operation. The Board wishes to clarify that the rule will require lenders to do only that which it expressly requires, although additional obligations may arise from other sources. For example, Federal associations and certain other lenders have disclosure obligations to applicants for home loans the purpose of which is to enable the applicant to understand fully the operation of the loan applied for, *see, e.g.*, 12 CFR 545.33(f), pt. 545 appendix, but such lenders do not generally have disclosure obligations to borrowers.

Alternatives. Commenters suggest four alternatives to the proposed rule. First, two commenters would permit prepayment penalties during the first five years of a loan but prohibit them thereafter. Second, one commenter suggests requiring management of institutional lenders to justify, and boards of directors to ratify, the imposition of each prepayment penalty. Third, one commenter suggests that either a due-on-sale clause or a prepayment-penalty clause—but not both—be permitted in a loan agreement.

The Board is aware of the first and third suggested alternatives, which are common approaches to the regulation of prepayment penalties. *See generally* G. Osborne, G. Nelson & D. Whitman, *Real Estate Finance Law* 379–83 (1979). Like the second suggested alternative, however, these alternatives are inconsistent with the Board's understanding of the benefit of the bargain for a lender and with the equities that flow from that understanding, which the Board has explained above. For this reason, the Board rejects these alternatives as inadequate approaches to the problem addressed in this rulemaking.

A fourth alternative would involve a two-tiered approach. First, a lender must give prompt written notice of whether it would permit assumption of a particular mortgage loan. Second, if a lender is willing to allow assumption of the loan, the lender must promptly process any assumption application. A lender could impose a prepayment penalty in two situations: if the borrower prepays despite the lender's written statement that it will permit assumptions, or if the borrower prepays after approval of an assumption application.

The Board believes that its final rule addresses the concern underlying this two-tiered approach. The Board is aware of the concern that borrowers are prepaying their home loans because lenders have informed them, either orally or in writing, that they will not permit loans to be assumed under any circumstance. The Board believes, however, not only that lenders must be given the opportunity to retain the benefit of their bargain but also that it is not unreasonable to place some responsibility in this regard upon borrowers. Thus, under the Board's final rule, a borrower is insulated against the imposition of a prepayment penalty if the lender is provided with a completed credit application for assumption of the home loan by a qualified transferee and the lender fails to approve that application.

Procedural suggestions. Commenters offer two procedural suggestions: that the comment period be extended and that the effective date of any final rule be no earlier than the date of its publication in the **Federal Register.**

The Board has responded to these requests by extending the comment period, by treating letters that have come to its attention as comments even through not submitted as such, and by considering even late-filed comments during this rulemaking. The Board has also notified the public of its intention, which it has given effect to in the final rule, to make the rule effective 30 days after publication in the **Federal Register.**

Final Regulatory Flexibility Analysis

Pursuant to section 3 of the Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164, 1167 (1980), the Board is providing the following regulatory flexibility analysis:

1. *Need for and objectives of the rule.* These elements are incorporated above in **SUPPLEMENTARY INFORMATION** regarding the rule.

2. *Issues raised by comments and agency assessment and response.* These elements are incorporated above in **SUPPLEMENTARY INFORMATION** regarding the rule.

3. *Significant alternatives minimizing small-entity impact and agency response.* The Board rejects the alternatives discussed above in **SUPPLEMENTARY INFORMATION** for the reasons given therein.

List of Subjects in 12 CFR Part 591

Banks, Banking, Preemption of state due-on sale laws, Mortgages, Imposition of prepayment penalties.

PART 591—PREEMPTION OF STATE DUE-ON-SALE LAWS

Accordingly, the Federal Home Loan Bank Board hereby amends Part 591, Subchapter G, Chapter V of Title 12, Code of Federal Regulations, as set forth below.

1. The statutory authority for Part 591 continues to read as follows:

Authority: Sec. 5, 48 Stat. 132 (12 U.S.C. 1464), as amended by sec. 401, 94 Stat. 160; sec. 311, 97 Stat. 1496; sec. 341, Pub. L. 97-320, 96 Stat. 1469, 1505-1507.

§ 591.2 [Amended]

2. Amend § 591.2(a) by adding at the end thereof the following sentence: "* * * 'Completed credit application' has the same meaning as *completed application for credit* as provided in § 202.2(f) of this title.".

3. Amend § 591.5 by redesignating paragraphs (b)(3) and (b)(4) as (b)(4) and (b)(5), respectively, and by revising paragraph (b)(2) and adding a new paragraph (b)(3), as follows. The introductory text of paragraph (b) is printed for the convenience of the reader.

§ 591.5 Limitation on exercise of due-on-sale clauses.

* * * * *

(b) *Specific limitations.* With respect to any loan on the security of a home occupied or to be occupied by the borrower,

* * * * * *

(2) A lender shall not impose a prepayment penalty or equivalent fee when the lender or party acting on behalf of the lender (i) declares by written notice that the loan is due pursuant to a due-on-sale clause or (ii) commences a judicial or nonjudicial foreclosure proceeding to enforce a due-on-sale clause or to seek payment in full as a result of invoking such clause.

(3) A lender shall not impose a prepayment penalty or equivalent fee when the lender or party acting on behalf of the lender fails to approve within 30 days the completed credit application of a qualified transferee of the security property to assume the loan in accordance with the terms of the loan, and thereafter the borrower transfers the security property to such transferee and prepays the loan in full within 120 days after receipt by the lender of the completed credit application. For purposes of this paragraph (b)(3), a "qualified transferee" is a person who qualifies for the loan under the lender's applicable underwriting standards and who occupies or will occupy the security property.

* * * * *

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 85-26829 Filed 11-12-85; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF COMMERCE

Economic Development Administration

13 CFR Part 309

[Docket No. 50724-5124]

General Requirements for Financial Assistance

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

ACTION: Interim rule.

SUMMARY: This rule amends § 309.3, "Nonrelocation" of the Economic Development Administration's regulations setting forth general requirements for financial assistance. The amendment narrows the present prohibition against relocation when financial assistance is extended to make it applicable to only business development projects under Section 202 of the Public Works and Economic Development Act (42 U.S.C. 3141).

DATES: Effective November 13, 1985. Comments by: January 13, 1986.

ADDRESS: Send comments to the Assistant Secretary for Economic Development, U.S. Department of Commerce, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, N.W., Room 7800B, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: James F. Marten, Deputy Chief Counsel for Operations and Administration, Economic Development Administration, U.S. Department of Commerce, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, N.W., Room 7009, Washington, D.C. 20230, (202) 377-5441.

SUPPLEMENTARY INFORMATION: EDA is amending 13 CFR Part 309, "General

Requirements for Financial Assistance." Section 309.3 "Nonrelocation" is being revised to limit the prohibition against relocation when financial assistance is extended to make it applicable to only business development projects.

The definition of "financial assistance" in paragraph (a) of section 309 is being amended to delete grants, technical assistance, and training, thus limiting it to loans and guarantees. The list of establishments in paragraph (b) subject to the prohibition is being amended to delete grantees, direct beneficiaries of grantees, and beneficiaries of contracts, thus limiting it to borrowers, lessees of borrowers, and affiliates, subsidiaries, or other entities under direct, indirect, or common control of borrowers of their lessees.

These changes are being made to conform section § 309.3 with a July 12, 1985, opinion by the General Counsel of the U.S. Department of Commerce, entitled "Open Audit Recommendations: Rock Hill, South Carolina, Project No. 04-01-03168, and Atlanta, Georgia, Project No. 04-01-03119." The opinion on page 7 states: "The nonrelocation prohibition is contained in Title II, section 202 of the (Public Works and Economic Development) Act (42 U.S.C. 3142). This section authorizes loans and loan guarantees for commercial business. . . . Because the language of the nonrelocation prohibition deals only with '[f]inancial assistance *under this section*'; i.e., section 202, the primary principle of statutory construction mandates that such a prohibition does not apply to grants under Title I (emphasis added)."

Existing § 309.3 goes beyond the statutory requirements as interpreted by the General Counsel in the opinion. Accordingly, it is being amended to conform to the General Counsel's opinion.

Under Executive Order 12291 the Department must judge whether a regulation is "major" within the meaning of Section 1 of the Order and therefore subject to the requirement that a Regulatory Impact Analysis be prepared. This regulation is not major because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, neither a preliminary nor final Regulatory Impact Analysis has to be or will be prepared.

Because this rule relates to grants, benefits, or contracts, it is exempt from all requirements of Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553).

No other law requires that notice and opportunity for comment be given for the rule.

Accordingly, the Department's General Counsel has determined and so certified to the Office of Management and Budget, that dispensing with notice and opportunity for comment is consistent with the APA and all other relevant laws.

However, because the Department is interested in receiving comments from those who will benefit from the amendments, this rule is being issued as interim final. Public comments on the interim final rule are invited and should be sent to the address listed in the "ADDRESS" section above.

Comments received by January 13, 1986 will be considered in promulgating a final rule.

Since notice and an opportunity for comment are not required to be given for this rule under section 553 of the APA (5 U.S.C. 553) or any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a), 604(a)), no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

Because this rule is exempt from the requirements of section 553 of the APA, it can be and is being made immediately effective upon publication.

This rule does not contain a collection of information for purposes of the Paperwork Reduction Act (Pub. L. 96-511).

List of Subjects in 13 CFR Part 309

Community development, Grant programs—community development, Loan programs—community development, Penalties.

For the reasons set forth above, 13 CFR Part 309 is amended as follows:

PART 309—[AMENDED]

1. The authority citation for Part 309 is revised to read as follows:

Authority: Sec. 701, Pub. L. 89-136, 79 Stat. 570 (42 U.S.C. 3211); sec. 1-105, DOC Organization Order 10-4, as amended (40 FR 56702, as amended).

2. 13 CFR Part 309 is amended by revising the first definition in paragraph (a) and revising paragraph (b) of § 309.3 to read as follows:

§ 309.3 Nonrelocation.

* * * * *

(a) *Definitions.* As used in this section:

"Financial assistance" under this section means loans and guarantees.

* * * * *

(b) Establishments relocating shall include:

(1) Borrowers,

(2) Lessees of borrowers, or

(3) Affiliates, subsidiaries, or other entities under direct, indirect, or common control of the foregoing.

* * * * *

Dated: November 7, 1985.

Mark R. Policinski,

Acting Assistant Secretary for Economic Development.

[FR Doc. 85-26979 Filed 11-12-85; 8:45 am]

BILLING CODE 3510-24-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 85-NM-55-AD; Amdt. 39-5169]

Airworthiness Directives: McDonnell Douglas Model DC-8-70 Series Aircraft, Equipped With an Auxiliary Power Unit (APU) in Accordance With STC SA1387NM

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adds a new airworthiness directive (AD) which requires removal and modification of the APU installed on DC-8-70 series aircraft. The action is prompted by an incident in which the exhaust door shut inadvertently, causing a blowout of the exhaust duct. As a result, exhaust gas discharged into the cargo compartment and caused wiring and structural damage. This action is necessary to minimize the potential of APU exhaust duct failure and resultant wiring and structural damage.

DATES: Effective December 19, 1985.

Compliance schedule as prescribed in the body of the AD, unless already accomplished.

ADDRESSES: The applicable service information may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, C1-750 (54-60). This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at 4344 Donald Douglas Drive, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Roy A. McKinnon, Aerospace Engineer, Propulsion Branch, ANM-140L, FAA, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California 90808; telephone (213) 548-2835.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include a new airworthiness directive (AD) to require removal and installation of a modified APU assembly on certain DC-8-70 series airplane was published as a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on July 1, 1985 (50 FR 27011). The comment period for the proposal closed August 12, 1985.

Interested persons have been afforded an opportunity to particiapte in the making of this amendment. Due consideration has been given to all comments received. Two comments were received.

One commenter offered no objection to adoption of the amendment.

Another commenter requested that, since the hazard exists only for airplanes modified by the installation of APU's in accordance with Supplementary Type Certificate (STC) SA1387NM, the applicability of the proposed AD should be limited to those airplanes. The FAA concurs with this request, and the final rule has been revised accordingly.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the amendment, with the changes previously noted.

It is estimated that 8 airplanes of U.S. registry will be affected by this AD. It will take approximately 18.5 manhours per APU to accomplish the required actions, and the average labor cost will be $40 per manhour. There is no charge for the kits or the APU modifications. Based on these figures, the total cost impact of this AD to U.S. operators will be $5,920.

For these reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic impact on a substantial number of small entities because few, if any, Model DC-8 airplanes are operated by small entities. A final evaluation has been prepared for this regulation and has been placed in the docket.

PART 39—[AMENDED]

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends Part 39 of the Federal Aviation Regulations as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive to § 39.13:

McDonnell Douglas: Applies to McDonnell Douglas Model DC-8-70 series airplanes, equipped with an auxiliary power unit in accordance with STC SA1387NM.

Compliance is required as indicated.

To preclude potential APU exhaust door failures and resulting wiring and structural damage, accomplish the following, unless already accomplished:

A. Within six (6) months after the effective date of this AD, complete the modifications defined in McDonnell Douglas DC-8-70 Service Bulletin 49-2, dated May 16, 1985, or later revisions approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region. The modifications involve removal of the APU; modification of the APU module and control boxes; revision of the APU control system sensing and fire control wiring; replacement of three generator phase circuit breakers; and the APU control and fuel supply circuit breakers; inspection of the wire routing; and reinstallation of the APU.

B. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

C. Alternate means of compliance which provide an acceptable level of safety may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to the McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, C1-750 (54-60). These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at 4344 Donald Douglas Drive, Long Beach, California.

This Amendment becomes effective December 19, 1985.

Issued in Seattle, Washington, on November 4, 1985.

Wayne J. Barlow,

Acting Director, Northwest Mountain Region.

[FR Doc. 85-26896 Filed 11-12-85; 8:45 am]

BILLING CODE 4910-13-M

---

14 CFR Part 71

[Airspace Docket No. 85-AEA-1]

Alteration of the Atlantic City, NJ, Control Zone

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final Rule; Request For Comments.

SUMMARY: The nature of this action is to cancel the existing Atlantic City, NJ Control Zone and designate two new control zones in the same area as the existing control zone.

DATES: Effective date: 0901 G.m.t., December 19, 1985.

Comments must be received on or before December 9, 1985.

ADDRESSES: Send comments on the proposal in triplicate to: Joseph Kelley, Acting Manager, Airspace and Procedures Branch, AEA-530, Federal Aviation Administration, Docket 85-AEA-1, Fitzgerald Federal Building (formerly Federal Building), John F. Kennedy International Airport, Jamaica, New York 11430.

The official dockets may be examined in the Office of Regional Counsel, Federal Aviation Administration, Fitzgerald Federal Building (formerly Federal Building), John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Airspace and Procedures Branch, AEA-530, Air Traffic Division, Federal Aviation Administration, Fitzgerald Federal Building, J.F.K. International Airport, Jamaica, New York 11430; Telephone: (718) 917-1228.

FOR FURTHER INFORMATION CONTACT: Joseph Kelley, Airspace and Procedures Branch, AEA-530, Air Traffic Division, Federal Aviation Administration, Fitzgerald Federal Building, J.F.K. International Airport, Jamaica, New York 11430; Telephone: (718) 917-1228.

SUPPLEMENTARY INFORMATION: The Municipal Authority of Atlantic City has stated intentions of establishing a control tower and the necessary weather reporting essentials to enhance air traffic movement in and out of Atlantic City Municipal/Bader Field, NJ. Atlantic City Municipal-Bader Field is

presently located within the Atlantic City, NJ Control Zone which is based on the Atlantic City International Airport located in Atlantic City, NJ, approximately eight miles northwest of Atlantic City Municipal/Bader Field.

Request for Comments on the Rule

Although this action is in the form of a final rule, which cancels the existing Atlantic City, NJ Control Zone and designates two new control zones in the same approximate area as the existing control zone, and thus was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the Federal Aviation Administration (FAA) will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this rule must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 85-AEA-1." The postcard will be date/time stamped and returned to the commenter. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments.

The Rule

The purpose of this amendment to § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to cancel the existing Atlantic City Control Zone, and to designate new control zones for Atlantic City Municipal/Bader Field and Atlantic City International Airport. This action will transfer control of the control zone surrounding Atlantic City Municipal/Bader Field to the control tower for that facility. Because the existing Atlantic City Control Zone includes both airports, the establishment of a separate control zone for each airport will have no significant effect on the total configuration of controlled airspace. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7460.6 dated January 3, 1984.

For the above reasons, I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary because these actions are minor amendments in which the public would not be particularly interested.

The FAA has determined that this amendment only involves an established body of technical regulation for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1976); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Control zones, Aviation safety.

The Amendment

PART 71—[AMENDED]

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

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

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

2. Section 71.171 is amended as follows:

Atlantic City, New Jersey [Revoked]

Atlantic City Muni/Bader Field, New Jersey: [New]

Within a three mile radius of the center (39° 21' 37" N, 74° 27' 29" W) of Atlantic City Muni/Bader Field; within two miles either side of the Atlantic City, New Jersey, VORTAC 136° radial, extending from the three mile radius zone 2.0 miles northwest; within two miles either side of a 270° bearing from a point 39° 21' 43" N, 74° 27' 46" W to a point 6.3 miles west.

Atlantic City International Airport, New Jersey [New]

Within a five mile radius of the center, (39° 27' 22" N, 74° 34' 41" W.) of Atlantic City International Airport, New Jersey; Within three miles each side of the Atlantic City VORTAC 303° radial, extending to 8.5 miles, excluding that airspace which is within the Atlantic City Bader/Field, New Jersey Control Zone.

Issued in Jamaica, New York, on October 4, 1985.

Timothy L. Hartnett,

Acting Director, Eastern Region.

[FR Doc. 85-26899 Filed 11-12-85; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 85-AGL-17]

Alteration of Transition Area; Watertown, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The nature of this action is to alter the Watertown, Wisconsin, transition area to accommodate a new NDB Runway 05 instrument approach procedure to Watertown Municipal Airport.

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

EFFECTIVE DATE: 0901 G.m.t., January 16, 1986.

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

SUPPLEMENTARY INFORMATION:

History

On Wednesday, September 4, 1985, the Federal Aviation Administration (FAA) proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to alter the Watertown, Wisconsin transition area (50 FR 35840).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6 dated January 2, 1985.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations alters the Watertown, Wisconsin transition area

to accommodate a new NDB Runway 05 instrument approach procedure to Watertown Municipal Airport.

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

List of Subjects in 14 CFR Part 71

Aviation safety/transition areas.

Adoption of the Amendment

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

PART 71—[AMENDED]

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

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

2. By amending § 71.181 as follows:

Watertown, WI

That airspace extending upward from 700 feet above the surface within an 8.5 mile radius of Watertown Municipal Airport (lat. 43° 10' 15" N., long. 88° 43' 20" W.).

Issued in Des Plaines, Illinois, on October 28, 1985.

Paul K. Bohr,

Director, Great Lakes Region.

[FR Doc. 85-26894 Filed 11-12-85; 8:45 am]

BILLING CODE 4910-13-M

---

14 CFR Part 71

[Airspace Docket No. 85-AGL-12]

Establishment of Transition Area; Knox, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The nature of this action is to establish the Knox, Indiana, transition area to accommodate a new VOR Runway 18 instrument approach procedure to Starke County Airport.

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

EFFECTIVE DATE: 0901 G.m.t. January 16, 1986.

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

SUPPLEMENTARY INFORMATION:

History

On Tuesday, September 10, 1985, the Federal Aviation Administration (FAA) proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish the Knox, Indiana Transition area (50 FR 36884).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6 dated January 2, 1985.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations establishes the Knox, Indiana transition area to accommodate a new VOR Runway 18 instrument approach procedure to Starke County Airport.

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

List of Subjects in 14 CFR Part 71

Aviation safety/transition areas.

Adoption of the Amendment

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

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

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

2. By amending § 71.181 as follows:

Knox, IN

That airspace extending upward from 700 feet above the surface within a 6.5 mile radius of Starke County Airport (lat. 41° 19' 51" N., long. 86° 39' 44" W.) and within 4 miles each side of the Knox VORTAC 337 radial, extending from the 6.5 mile radius area to 8.5 miles northwest of the airport.

Issued in Des Plaines, Illinois, on October 28, 1985.

Paul K. Bohr,

Director, Great Lakes Region.

[FR Doc. 85-26893 Filed 11-12-85; 8:45 am]

BILLING CODE 4910-13-M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket No. 9161]

Hospital Corporation of America; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: This final order requires the nation's largest for-profit hospital chain, based in Nashville, Tenn., to divest North Park Hospital and Diagnostic Center Hospital, both in Hamilton County, Tenn., and any medical office buildings associated with the hospitals. The divestitures must be to different acquirers and obtain Commission approval. Respondent is also required to terminate its management contract with Downtown General Hospital, also in Hamilton County, and divest related real estate to a Commission-approved acquirer. Further, respondent is required to obtain FTC approval for any future acquisitions of certain hospitals in the Chattanooga, Tenn., area or any hospital meeting conditions specified in the order.

DATES: Complaint issued July 30, 1982. Final Order issued Oct. 25, 1985.*

FOR FURTHER INFORMATION CONTACT: M. Elizabeth Gee, FTC/B-823, Washington, D.C. 20580. (202) 724-1303.

SUPPLEMENTARY INFORMATION: In the Matter of Hospital Corporation of America, a corporation. The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Acquiring Corporate Stock or Assets: S 13.5 Acquiring corporate stock or assets. Subpart—Corrective Actions and/or Requirements: S 13.533 Corrective actions and/or requirements.

List of Subjects in 16 CFR Part 13

Hospitals, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

United States of America, Before the Federal Trade Commission

Commissioners: James C. Miller III, Chairman, Patricia P. Bailey, George W. Douglas, Terry Calvani, Mary L. Azcuenage.

In the matter of Hospital Corporation of America, a corporation; Docket No. 9161.

Final Order

I

This matter has been heard by the Commission upon the appeals of Complaint Counsel and respondent Hospital Corporation of America from the Initial Decision and upon briefs and oral argument in support of and in opposition to the appeals. For the reasons stated in the accompanying Opinion, the Commission has determined to affirm in part and reverse in part the Initial Decision. Accordingly, the Commission enters the following Order.

Definitions

It is ordered that for purposes of this Order the following definitions shall apply:

A. "HCA" means Hospital Corporation of America, a corporation organized under the laws of Tennessee, with its principal executive office at One Park Plaza, Nashville, Tennessee 37203, and its directors, officers, agents, employees, and representatives, and its subsidiaries, divisions, affiliates, successors, and assigns.

B. "HAI" means Hospital Affiliates International, Inc.

C. "County" also includes a county equivalent, such as a parish in Louisiana.

D. "Acute care hospital," herein referred to as "hospital," means a health facility, other than a federally owned facility, having a duly organized governing body with overall administrative and professional responsibility and an organized professional staff that provides 24-hour inpatient care, as well as outpatient services, and which has as a primary function the provision of inpatient services for medical diagnosis, treatment, and care of physically injured or sick persons with short-term or episodic health problems or infirmities.

E. "Acquire any hospital" means to directly or indirectly acquire all or any part of the stock or assets of any hospital, or enter into any arrangement by which HCA obtains direct or indirect ownership, management or control of any hospital or any unit of such hospital, including a lease of or management contract for any such hospital or unit of such hospital.

F. "Operate a hospital" means to own, lease or manage an acute care hospital.

G. "MSA" and "PMSA" mean, respectively, a Metropolitan Statistical Area, and a Primary Metropolitan Statistical Area, as defined as of July 1, 1983, by the Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President.

H. The "Chattanooga Urban Area" means that geographic area comprising Hamilton County, Tennessee and Dade, Walker and Catoosa counties in Georgia.

I. "Person" means any natural person, partnership, corporation, company, association, trust, joint venture, or other business or legal entity, including any governmental agency.

II

A. It is ordered that, within twelve (12) months from the date this Order becomes final, HCA shall divest, absolutely and in good faith, at no minimum price:

(1) North Park Hospital in Hamilton County, Tennessee, and all assets, properties, lands, licenses, leases, and other rights and privileges in connection with the hospital, both tangible and intangible. The divestiture required by this provision of this Order specifically shall include any medical office building owned by HCA that is adjacent to, affiliated with, or operated in connection with, North Park Hospital, as well as the plot of land on which each such medical office building is situated. The purpose of this divestiture is to establish North Park Hospital as a viable competitor, and to restore competition in the area. The divestiture shall be subject to the prior approval of the Federal Trade Commission;

(2) Diagnostic Center Hospital in Hamilton County, Tennessee, and all assets, properties, lands, licenses, leases, and other rights and privileges in connection with the hospital, both tangible and intangible, that HCA acquired from HAI, together with any subsequent improvements in, or additions to, any such assets or properties. The divestiture required by this provision of this Order specifically shall include any medical office building owned by HCA that is adjacent to, affiliated with, or operated in connection with, Diagnostic Center Hospital, as well as the plot of land on which each such medical office building is situated. The purpose of this divestiture is to reestablish Diagnostic Center Hospital as a viable competitor, and to restore competition in the area. The divestiture shall be to a person other than the person to whom divestiture is made under Section II., paragraph A. (1) of this Order, and shall be subject to the prior approval of the Federal Trade Commission.

Pending divestiture, HCA shall take all measures necessary to maintain North Park Hospital and Diagnostic Center Hospital in their present conditions and to prevent any deterioration, except for normal wear and tear, of any of the assets to be divested, so as not to impair the present operating abilities or market value of the hospitals or the other assets to be divested.

B. It is ordered that, within twelve (12) months from the date this Order becomes final, HCA shall divest any and all interest in, and divest or terminate all contracts or arrangements whereby it manages, Downtown General Hospital in Hamilton County, Tennessee, together with all assets, properties, lands, licenses, leases, and other rights and privileges in connection with the hospital, both tangible and intangible, that HCA acquired from HAI, together with any subsequent improvements in, or additions to, such assets or properties. The divestiture required by this provision of this Order specifically shall include the plot of land on which Downtown General Hospital is situated, as well as the medical office building owned by HCA that is adjacent to Downtown General Hospital, and the plot of land on which such medical office building is situated. The purpose of this provision is to reestablish Downtown General Hospital as a viable competitor, and to restore competition in the area. Any divestiture pursuant to this provision, other than simple and unconditional termination of management contracts, leases, or other similar arrangements, shall be subject to the prior approval of the Federal Trade Commission.

*Copies of the Complaint, Initial Decision and Opinion of the Commission are filed with the original document.

Pending divestiture or termination, HCA shall take all measures necessary, within its responsibilities and authority, to maintain Downtown General Hospital in its present condition and to prevent any deterioration, except for normal wear and tear, of any asserts to be divested, so as not to impair the present operating abilities or market value of the hospital or the other assets to be divested.

III

A. If HCA has not divested all of the properties, assets, contracts, arrangements or enterprises required to be divested pursuant to Section II of this Order within the 12-month period provided therein, the Federal Trade Commission may select a trustee to effect any ordered divestitures yet to be accomplished. The trustee shall be a person with experience and expertise in acquisitions and divestitures. If the Federal Trade Commission should elect to appoint a trustee, it shall not be precluded from seeking civil penalties and other relief available to it for any failure by HCA to comply with this Order. If the Federal Trade Commission should not elect to appoint a trustee under this Section III of this Order, it shall not be precluded from seeking civil penalties, the appointment by the courts of a trustee to effect the divestitures, and other relief available to it, for any failure by HCA to comply with this Order.

B. Any trustee appointed by the Federal Trade Commission pursuant to this Section shall have the following powers, authority, duties, and responsibilities:

(1) The trustee shall have the exclusive power and authority to divest any properties, assets, or enterprises required to be divested pursuant to Section II of this Order that have not been divested by HCA within the time period for the divestitures provided therein. The trustee shall have twelve (12) months from the date of appointment to accomplish the divestitures, which shall be subject to the prior approval of the Federal Trade Commission. If, however, at the end of the twelve-month period the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Federal Trade Commission. In addition, any delays in divestiture caused by HCA shall extend the time for divestiture in accordance with the delay caused.

(2) The trustee shall have full and complete access to the personnel, books, records, and facilities of any property, asset, or enterprise that the trustee has the duty to divest, and HCA shall develop such financial or other information relevant to the properties, assests, or enterprises to be divested as such trustee may reasonably request. HCA shall cooperate with the trustee, and shall take no action to interfere with or impede the trustee's accomplishment of the divestitures.

(3) The power and authority of the trustee to divest shall be at the most favorable price and terms available consistent with this Order's absolute and unconditional obligation to divest at no minimum price, and the purposes of the divestitures as stated in Section II of this Order.

(4) The trustee shall serve, without bond or other security, at the cost and expense of HCA on such reasonable and customary terms and conditions as the Federal Trade Commission may set. The trustee shall have authority to retain, at the cost and expense of HCA, such consultants, attorneys, investment bankers, business brokers, accountants, appraisers, and other representatives and assistants as are reasonably necessary to assist in the divestitures. The trustee shall account for all monies derived from the sale and all expenses incurred. After approval by the Federal Trade Commission of the account of the trustee, including fees for his or her services, all remaining monies shall be paid to HCA and the trustee's power shall be terminated. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee divesting the trust property.

(5) HCA shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, or liabilities to which the trustee may become subject, arising in any manner out of, or in connection with, the trustee's duties under this Order, unless the Federal Trade Commission determines that such losses, claims, damages, or liabilities arose out of the misfeasance, gross negligency, or the willful or wanton acts or bad faith of the trustee.

(6) Promptly upon appointment of the trustee and subject to the approval of the Federal Trade Commission, HCA shall, subject to the Federal Trade Commission's prior approval and consistent with provisions of this Order, execute a trust agreement that transfers to the trustee all rights and powers necessary to permit the trustee to cause the divestitues.

(7) If the trustee ceases to act or fails to act diligently, the Federal Trade Commission shall appoint a substitute trustee.

(8) The trustee may ask the Federal Trade Commission to issue, and the Federal Trade Commission may issue, such additional orders or directions as may be necessary and appropriate to accomplish the divestitures required under this Order.

(9) The trustee shall have no obligation or authority to operate or maintain any of the properties, assets, contracts, arrangements or enterprises required to be divested pursuant to Section II of this Order.

(10) The trustee shall report in writing to HCA and the Federal Trade Commission every sixty (60) days concerning the trustee's efforts to accomplish divestiture.

IV

It is further ordered that, for a period of ten (10) years from the date this Order becomes final, HCA shall not, without the prior approval of the Federal Trade Commission, acquire any hospital, as defined in this Order, if the hospital to be acquired is within the Chattanooga Urban Area, as defined in this Order.

Provided, however, that no acquisition of a hospital by purchase shall be subject to this Section IV of this Order if the consideration to be paid for the purchase of the hospital or any rights or interest therein, including assumption by HCA of any liabilities of its present owners, does not exceed one million dollars ($1,000,000), and provided that no lease or management arrangement shall be subject to this Section IV of this Order if the fair market value of the hospital to be leased or managed does not exceed one million dollars ($1,000,000).

V

It is further ordered that for a period of ten (10) years from the date this Order becomes final, HCA shall not, without providing advance notification to the Federal Trade Commission, acquire any hospital, as defined in this Order, if:

A. The hospital to be acquired is within an MSA or a PMSA in which HCA already operates a hospital and in which HCA, immediately after the acquisition, would operate hospitals that combined have a twenty (20) percent or more share of the licensed acute care hospital beds within that MSA or PMSA; or

B. The hospital to be acquired is not within an MSA or a PMSA but is within a county in which HCA already operates a hospital and in which HCA, immediately after the acquisition, would operate hospitals that combined have a twenty (20) percent or more share of the licensed acute care hospital beds within that county; or

C. The hospital to be acquired is (1) not within an MSA or a PMSA or a county in which HCA already operates a hospital, but is within thirty (30) miles of a hospital which HCA already operates in another MSA or PMSA or county, and (2) the hospital to be acquired and any hospital(s) that HCA operates combined have a twenty (20) percent or more share of the licensed acute care hospital beds in the area within thrity (30) miles of the midpoint between the hospital to be acquired and any hospital operated by HCA.

The notification required of HCA by this Section V of this Order shall not require additional notification by HCA to the Federal Trade Commission of any acquisition for which notification is required to be made, and has been made, pursuant to section 7A of the Clayton Act, 15 U.S.C. 18a, or for which prior approval by the Federal Trade Commission is required, and has been requested, pursuant to Section IV of this Order. Such advance notification shall be provided when HCA's Board of Directors or Executive Committee, or any individual or entity that is

authorized to act on HCA's behalf in such acquisitions, authorizes issuance of a letter of intent or enters into an agreement to make such an acquisition, whichever is earlier.

The notification required by this section V of this Order shall be the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations, as amended, and shall be prepared and transmitted in accordance with the requirements of that part. The notification required by this section V of this Order shall apply to HCA and shall not apply to any party that HCA seeks to acquire. However, HCA shall provide at the same time of the filing of the Notification and Report Form supplemental information, either in HCA's possession or reasonably available to HCA, relating to the hospital to be acquired, the HCA hospital in that geographic area, and identification and assessment of the area hospital market. Such supplemental information should include, where available, patient flow data, annual management and strategic plans, hospital utilization and revenue data, and documents relating to market share, formulation of hospital prices, competitive interaction among area hospitals, implementation of certificate of need standards in the area, planned efficiencies, relations with third-party payors, and physician admitting patterns.

HCA shall comply with reasonable requests by the Commission staff for additional information within fifteen (15) days of service of such requests.

Any acquisition subject to this Section V of this Order, involving an arrangement to lease, manage, or control a hospital, shall be fully described in the notification regardless of whether the acquisition involves the acquisition of any stock or assets of a hospital.

Provided, however, that no acquisition of a hospital by purchase shall be subject to this Section V of this Order if the consideration to be paid for the purchase of the hospital or any rights or interest therein, including assumption by HCA of any liabilities of its present owners, does not exceed one million dollars ($1,000,000), and provided that no lease or management arrangement shall be subject to this Section V of this Order if the fair market value of the hospital to be leased or managed does not exceed one million dollars ($1,000,000).

It is further ordered that HCA shall, within sixty (60) days after the date this Order become final and every sixty (60) days thereafter until it has fully complied with the provisions of Section II of this Order, submit in writing to the Federal Trade Commission a report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with these provisions.

Such compliance reports shall include, in addition to any other information that the staff of the Federal Trade Commission may request, a summary of all contacts and negotiations with potential purchasers of the stock, assets, contracts, or other rights or interests to be divested under this Order, the identity and address of all such potential purchasers, and copies of all written communications to and from such potential purchasers.

HCA shall submit such further written reports as the staff of the Federal Trade Commission may, from time to time, request in writing to assure compliance with this Order.

VII

It is further ordered that HCA, upon written request of the Secretary of the Federal Trade Commission or the Director of the Bureau of Competition of the Federal Trade Commission made to HCA at its principal office, for the purpose of securing compliance with this Order, and for no other purpose, and subject to any legally recognized privilege, shall permit duly authorized representatives of the Federal Trade Commission or the Director of the Bureau of Competition:

(1) Reasonable access during the office hours of HCA, which may have counsel present, to those books, ledgers, accounts, correspondence, memoranda, reports, and other records and documents in HCA's possession or control that relate materially and substantially to any matter contained in this Order; and

(2) An opportunity, subject to the reasonable convenience of HCA, to interview officers or employees of HCA, who may have counsel present, regarding such matters.

VIII

It is further ordered that HCA shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed corporate change, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation that may affect compliance with the obligations arising out of this Order.

By the Commission.

Emily H. Rock,

Secretary.

Issued: October 25, 1985.

October 25, 1985

Hospital Corporation of America, Docket No. 9161

Statement of Commissioner Bailey Concurring in Part and Dissenting in Part

As in last year's decision in *American Medical International*,[1] I agree with the Commission majority on product and geographic market definitions, and the finding of liability. Also as in *AMI*, I must dissent from a remedy which stops short of requiring prior approval for a certain limited class of future mergers, imposing instead an almost purely symbolic duty of prior notification.

Indeed, this dissent is so completely parallel in substance to my concerns in *AMI* that I will not repeat them here. There is, however, one important difference between the two cases which requires further discussion. In *AMI* it seemed at least possible that the Commission's standards for prior approval could produce a prior approval order in some future case. Unfortunately, it is now abundantly clear that the *AMI* test, as interpreted in *HCA*, is a mirage, at least as to prior approval which extends beyond the geographic market at issue in the litigation.

Consider: here, as in *AMI*, we have a company with an aggressive corporate policy of growth through acquisition [2] which engendered a series of takeovers in a local market characterized by high concentration and high entry barriers. We have every reason to suppose that HCA will carry out its policy in similarly situated markets in the future.[3] We also know that many of these mergers, no matter what their actual impact on a local market, may be priced at a level which does not trigger Hart-Scott-Rodino reporting requirements; consequently the Commission cannot call upon that Act's provisions to forestall the merger until adequate

[1] American Medical International, Inc., Docket No. 9158 (FTC July 2, 1984) ("AMI").

[2] *See, e.g.*, CX 110Z-28; CX 117-J, Z-103, Z-114; Williamson Tr. 3256.

[3] In Appendix C to their appeal brief Complaint Counsel list twenty markets where HCA owns, leases or operates hospitals. The HHI's for these markets range from 1698 to 3246; four-firm concentration ratios range from 75.3% to 98.6%; HCA's current market share ranges from 3.7% to 45.4%.

information for antitrust analysis is received.

In these circumstances, "fencing-in" seems appropriate. The Commission should want to evaluate *and be able to block* future HCA mergers which could adversely affect a vulnerable market. The *AMI* opinion seemed to say that, if a screen could be devised which would filter out safe markets, a prior approval order would be acceptable.[4] In my opinion, Complaint Counsel have produced such an order. They do not ask for a prior approval clause which blankets the nation, or even specific regions. Instead, prior approval would be required for an HCA hospital acquisition outside the Chattanooga area *only* if:

(1) HCA is already operating a hospital in the market or would end up operating two or more hospitals as a result of two or more simultaneous acquisitions from different persons;

(2) the acquisition would result in a Herfindahl Index in a local hospital market of over 1800;

(3) the acquisition would increase the Herfindahl Index by 100 or more points; and

(4) barriers to entry are likely to be high due to state certificate of need laws (which require government approval for new entry into the market) (Complaint Counsel's Appeal Brief at 39 and Appendix A)

These standards parallel those of the Department of Justice Merger Guidelines. It might be argued that this test presents two practical difficulties for respondent: how to tell which is a local market, and how to get "sales" data from which to calculate the Herfindahl Index; but Complaint Counsel have anticipated these queries. Their proposed order specifies that market shares be calculated upon state-licensed acute care bed capacity, which is public information, and that the market be deemed to be the Metropolitan Statistical Area ("MSA") or Primary Metropolitan Statistical Area ("PMSA"), likewise public knowledge. These geographic and product market surrogates are used *only* to determine the necessity of filing with the Commission; they need not be used in the substantive evaluation of the merger. To my mind this is an order which is sensitive to respondent's reporting burdens and yet serves the Commission's enforcement needs.

Nevertheless, the Commission rejects this approach, showing that all along the true parameters of the *AMI* test were contained in the discussion of the procompetitive effects of AMI's presence as a potential purchaser in the market, and the alleged unwarranted hobbling effect of a prior approval requirement on hospital purchase negotiations where time is of the essence. *AMI*, slip op. at 60.

In the *HCA* opinion, the Commission is so solicitous of respondent's reporting "burden" that only a full-blown proof of the vulnerability of other local markets, extraneous to the case at hand, will justify asking respondent to provide the information described above. *See, e.g., HCA* slip op. at 113–116. In other words, respondents will not be "burdened" with the duty to provide a few pieces of publicly available data before they merge, but Commission staff are asked to assume the vastly greater burden of expanding their litigated proofs of geographic market definition, barriers to entry, concentration ratios, testimony as to the nature of competition—in short, all the factors which are necessary before a certain local market can be defined and determined to be at risk from a potential future merger.

We have recently revised our procedural rules to encourage all parties to streamline and expedite administrative trials. 50 FR 41485 (Oct. 11, 1985). Why then are we now unnecessarily complicating a merger case by requiring explorations into extraneous markets? The burden on our resources, not to mention the risk to the case in chief, is not justified by the increasingly faint possibility of obtaining a prior approval order. On the Commission's commitment to such prior approval remedies, at least where hospital mergers are concerned, the time has come to point out that the emperor is wearing no clothes.

October 25, 1985.

Hospital Corporation of America, Docket No. 9161

Concurring Statement of Commissioner Azcuenaga

I concur in the result regarding liability and, based upon the recent precedent in *American Medical International, Inc.*, Docket No. 9158 (FTC July 2, 1984), remedy.

[FR Doc. 85–26930 Filed 11–12–85; 8:45 am]

BILLING CODE 6750-01-M

[4] In *AMI* the majority rejected fencing-in with the following language:

"Our reading of the record does not indicate any basis for defining the parameters of these markets, determining concentration levels or changes in concentration levels in these markets as a result of the acquisitions that are taking place in this industry, or assessing whether the acquisitions have had either the effect of entrenching monopolists or increasing competition between market participants." Slip op. at 59.

16 CFR Part 13

[Docket No. C-3171]

Wright-Patt Credit Union, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent Order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order requires a Fairborn, Ohio, credit union, among other things, to cease failing to tell consumers, when applications for credit are denied because of information contained in credit reports (including non-derogatory information), that the adverse action had been taken on the basis of such information; and provide the rejected credit applicants with the names and addresses of the credit bureaus that had submitted the reports. The order further bars the organization from failing to identify applications submitted between Sept. 1, 1983 and the date of issuance of the order, for which adverse action had been taken on the basis of information obtained from a consumer reporting agency, and to send to those rejected applicants who had not been given the legally-required disclosures, a copy of the notification letter attached to the order as Appendix A.

DATE: Complaint and order issued Oct. 21, 1985.*

FOR FURTHER INFORMATION CONTACT: Eileen M. Harrington, FTC/I–500, Washington, D.C. 20580. (202) 724–1188.

SUPPLEMENTARY INFORMATION: On Thursday, May 9, 1985, there was published in the **Federal Register**, 50 FR 19536 a proposed consent agreement with analysis In the Matter of Wright-Patt Credit Union, Inc., a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions of objections regarding the proposed form of order.

A comment was filed and considered by the Commission. The Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16

*Copies of the Complaint and the Decision and Order are filed with the original documents.

CFR Part 13, are as follows: Subpart—Collecting, Assembling, Furnishing or Utilizing Consumer Reports: § 13.382 Collecting, assembling, furnishing or utilizing consumer reports; § 13.382–5 Formal regulatory and/or statutory requirements; § 13.382–5(a) Fair Credit Reporting Act. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; § 13.533–20 Disclosures; 13.533–37 Formal reglatory and/or statutory requirements; 13.533–45 Maintain records. Subpart—Neglecting, Unfairly or Deceptively, To Make Material Disclosure: § 13.1852 Formal regulatory and/or statutory requirements.

List of Subjects in 16 CFR Part 13

Consumer credit, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Emily H. Rock,

Secretary.

[FR Doc. 85–26929 Filed 11–12–85; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RM79–76–214 etc.]

18 CFR Part 271

High-Cost Gas Produced From Tight Formations; Wyoming

Issued: November 6, 1985.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order Denying Request for Rehearing and Petition to Reopen and Remand.

SUMMARY: Under section 107(c)(5) of the Natural Gas Policy Act of 1978, the Federal Energy Regulatory Commission designates certain types of gas as high-cost gas. High-cost gas is produced under conditions which present extraordinary risks or costs and once designated may receive an incentive price. Under section 107(c)(5), the Commission issued a rule designating natural gas produced from tight formations as high-cost gas. Jurisdictional agencies may submit recommendations of areas for designation as tight formations. In Order No. 338, issued October 7, 1983, 48 F.R. 46,266 (October 12, 1983) the Commission designated certain formations located in Fremont County, Wyoming, as tight formations. Here, the Federal Energy Regulatory Commission denies Montana-Dakota Utilities Company's request for rehearing of Order No. 338 and its petition to reopen the record and to remand the proceeding to BLM.

DATE: This order was issued November 6, 1985.

FOR FURTHER INFORMATION CONTACT: Frederick W. Peters, (202) 357–9115; or Victor H. Zabel, (202) 357–8616.

Order No. 338–A; Denying Request for Rehearing and Petition To Reopen and Remand

Before Commissioners: Raymond J. O'Connor, Chairman; A.G. Sousa and Charles G. Stalon.

High Cost Gas Produced from Tight Formations, Docket Nos. RM79–76–214, RM79–76–215, RM79–76–228, RM79–76–229, (Wyoming-14 & 15).

Issued: November 6, 1985.

Montana-Dakota Utilities Company (MDU) seeks rehearing of Commission Order No. 338 [1] or, in the alternative, reopening of the record and remand of the subject matter of the order to the United States Department of the Interior, Bureau of Land Management (BLM). For the reasons set forth below, the request for rehearing and petition to reopen and remand are denied.

Background

On October 7, 1983, the Commission issued Order No. 338, adopting the recommendation of BLM that the Frontier, Muddy, Dakota, and Lakota formations, located in Fremont County, Wyoming, be designated as tight formations pursuant to section 107(c)(5) of the Natural Gas Policy Act of 1978 (NGPA) and section 271.703 of the Commission's regulations. The Muddy, Dakota and Lakota formations are known collectively as the Dakota Group. BLM's recommendation was based on information supplied by ARCO Oil and Gas Company, a Division of Atlantic Richfield Company (ARCO). MDU filed timely comments with the Commission in opposition to BLM's recommendation. The Commission adopted BLM's recommendation in Order No. 338. On November 7, 1983, MDU filed a timely request for rehearing and stay of the order [2] and on March 27, 1984, MDU filed a petition requesting the Commission to reopen the record and remand the proceeding to BLM.[3]

Notice of MDU's petition was published in the **Federal Register** on May 30, 1984 (49 FR 22,497). On June 5, 1984, MDU requested a public hearing. On June 4 and 8, 1984, the Wyoming Public Service Commission (Wyoming) and the South Dakota Public Utilities Commission (South Dakota) filed notices of intervention. Wyoming objected to the possibility of increased gas costs and therefore supported MDU's petition. South Dakota also supported MDU's petition to reopen and remand. On June 14, ARCO filed comments protesting MDU's petition to reopen and remand. MDU also filed comments in support of its own petition. By operation of Rule 214, Wyoming and South Dakota were granted intervenor status upon the filing of their notices. On September 14, the Shoshone Indian Tribe and the Arapahoe Indian Tribe of the Wind River Indian Reservation jointly filed a late motion to intervene in opposition to MDU's petition to reopen and remand. For good cause shown, the late filed motion to intervene is granted pursuant to Rule 214(d).

Order No. 338

Under applicable NGPA regulations [4], it is the Commission's policy to designate as a tight formation any formation recommended by a jurisdictional agency if the Commission finds that substantial evidence in the record submitted by the jurisdictional agency shows that the average gas permeability, stabilized pre-stimulation natural gas flow rate, and the pre-stimulation crude oil flow rate of the formation do not exceed designated limits.[5] However, under § 271.703(c)(2)(i)(D) of the regulations, if all or part of the formation was authorized to be developed by infill drilling [6] prior to the date of recommendation, and if the jurisdictional agency has information indicating that the formation or portion thereof subject to infill drilling can be developed absent the incentive price, then the formation or portion thereof

[1] Docket Nos. RM79–76–151 and 152 (Wyoming 14 & 15), 48 FR 46268 (Oct. 12, 1983).

[2] On December 2, 1983, the Commission issued an Order Granting Rehearing for Purposes of Further Consideration in Docket Nos. RM79–76–214 and RM79–76–215, 48 F.R. 55,437 (Dec. 13, 1983), solely for the purpose of affording further time to consider the issues raised in MDU's petition. No action was taken on MDU's request for a stay. MDU's request for a stay is denied by this order.

[3] MDU's request to reopen and remand was assigned Docket Nos. RM79–76–228 and 229.

[4] 18 CFR 271.703(c) (1985).

[5] Oil flow rates are not at issue since the subject formations are not productive of crude oil.

[6] As defined in § 271.703(b)(6), "infill drilling" means drilling in a substantially developed formation which is in excess of normal spacing requirements and which is permitted by the responsible state authority in order to provide more efficient and effective drainage of reservoirs in the formation.

shall not be included in the recommendation.

In Order No. 338, the Commission determined that despite MDU's objections, the recommended formations met the permeability and gas flow rate guidelines set forth in § 271.703(c)(2)(i)(A) and (B) of the regulations and that there were no infill drilling authorizations applicable to any portion of any of the formations. Consequently, the Commission adopted BLM's recommendation. The Commission's findings with respect to permeability, natural gas flow rate, and infill drilling may be summarized as follows.

1. *Permeability.* Permeability may be tested by several methods, two of which are core analysis and pressure build-up analysis. Extensive core analysis data were available for both the Frontier formation and the Dakota Group. A summary of core analysis data was derived by geometrically averaging multiple permeability values measured within the pay zones of eight well bores, covering both the Frontier formation and the Dakota Group.[7] ARCO then selected and submitted to BLM 23 geometrically derived permeability values representative of the subject formations. The 23 values were arithmetically averaged by the Commission to obtain the average formation permeability. Actual core analysis data were not submitted to BLM. Pressure build-up data for the Frontier formation and the Dakota Group were significantly less extensive than the core analysis data and were not utilized by BLM.

MDU argued that the core analysis data relied on by BLM should have been adjusted by a correction factor based on the omitted pressure build-up data. In Order No. 338, the Commission concluded that the intervals tested by pressure build-up analysis were not identical to those tested by core analysis, no reliable relationship existed between the analyses, and a correction factor therefore was not appropriate. The statistically more representative core analysis was relied on to assess permeability of both the Frontier formation and the Dakota Group. With respect to averaging methodologies, the Commission has never required that the permeability values in individual well bores be determined solely by arithmetic averaging. Hence, ARCO's method of geometrically averaging permeability values within the well bore is permissible.

[7] The geometric mean average of a statistically diverse sample containing extreme high and low values will be lower than the arithmetic average of the same sample.

2. *Natural Gas Flow Rate.* Section 271.703(c)(2)(i)(B) specifies maximum allowable production rates based on depth of formations. Drill stem data establishing the stabilized pre-stimulation flow rate of the subject formations were submitted by ARCO demonstrating that the flow rates from these formations did not exceed the levels prescribed by § 271.703(c)(2)(i)(B) of the regulations. These data were accepted by BLM for purposes of its recommendation, and were adopted by the Commission in Order No. 338.

MDU argued that certain data concerning pre-stimulation flow rates which showed flow rates in excess of those permitted by the Commission's regulations were available to ARCO but were not submitted to BLM. In Order No. 338, the Commission concluded that the data referred to by MDU, available on Petroleum Information scout cards, were based on drill stem testing in which the stabilized flow rate had not been established, as is required by the Commission's regulations. Further, BLM has advised the Commission that it considers scout cards to be unreliable for the purpose of determining stabilized flow rates.[8] Consequently, the Commission declined to rely on the scout card data.

3. *Infill Drilling.* Jurisdictional agencies typically require that production wells be spaced on drilling units so that no more than one well per unit is producing gas from a given formation. Several wells may be drilled within the same surface unit without violating spacing rules provided the wells are producing gas from different formations. In accordance with local custom and practice, the number of gas wells in the recommended formations is limited to one well per 320 acre drilling unit.[9] In Order No. 338, the Commission rejected MDU's contention that infill drilling had occurred in the recommended formations, thereby disqualifying them for designation as tight formations. The Commission recognized that the formations are located entirely within the Wind River Indian reservation and are therefore not subject to state infill drilling orders or infill drilling restrictions contained in the Commission's regulations. The Commission further recognized and adopted BLM's determination that the number of wells drilled into the formations did not exceed one well per 320-acre drilling unit. The Commission therefore concluded that no infill drilling had occurred in the recommended formations.

[8] *See* letter dated May 19, 1983, from the Bureau of Land Management to the Federal Energy Regulatory Commission.

[9] There are no federal spacing rules *per se*. As a matter of common practice, however, BLM often follows state spacing requirements but does not technically subject its lessees to such requirements.

MDU's Arguments

Both MDU's request for rehearing and its petition to reopen and remand are based on MDU's assertion that ARCO should have been required to submit additional data to BLM in order to satisfy the substantial evidence requirement of section 506(a)(4) of the NGPA, and that different statistical methodologies should have been employed by BLM in determining the permeability of the formations in question. Specifically, MDU asserts that ARCO should have submitted actual core analysis data, rather than summary data, as well as all pressure build-up data, drill stem tests, and flow rate data available to ARCO. In its petition to reopen, MDU also argues that despite the non-existence of well spacing requirements affecting the subject acreage, the Commission must impute a well spacing requirement in order to determine whether the recommended area has been substantially developed for purposes of applying the infill drilling criterion contained in the Commission's regulations. Finally, MDU challenges the lack of record evidence supporting the need for an incentive price for development of the recommended formations, given the development history of the formations.

Discussion

Upon review of MDU's request for rehearing and petition to reopen, the Commission concludes that MDU's arguments are without merit and do not warrant modification of Order No. 338. MDU has presented no new facts or arguments with regard to the flow rate issue. This issue was fully considered in Order No. 338 and no further comment on this issue is necessary. However, MDU's arguments concerning the issues of permeability, infill drilling and the Commission policy of determining need for tight formation incentive pricing on a generic basis merit further consideration and comment.

MDU's argument that actual core analysis data, rather than a summary of the data, must be submitted to establish permeability values is rejected. The Commission does not require actual core analysis data to be submitted for the purpose of evaluating formation permeability and has approved numerous recommendations based on representative summary data. MDU has not demonstrated that the summary data

relied on by BLM, and adopted by the Commission in Order No. 338, are in any way unrepresentative of the permeability of the subject formations. The Commission reaffirms its conclusion that the summary data relied upon by BLM constitutes substantial evidence supporting the conclusion that the subject formations meet the permeability standards prescribed in § 271.703(c)(2)(i)(A) of the Commission's regulations.

With respect to the issue of infill drilling, MDU argues that the Commission's findings in Order No. 338 are in conflict with standards applied by the Commission in Order No. 148,[10] involving certain formations located in Colorado. MDU argues that in Order No. 148 the Commission found that portions of a recommended tight formation were substantially developed because of additional drilling which took place prior to the date of the recommendation, and that such drilling constitued infill drilling within the meaning of the Commission's regulations. MDU argues that the Commission should determine whether portions of the Dakota Group and Frontier formation have been "substantially developed" as that term is described in Order No. 148.

In Order No. 148, the Commission found evidence indicating that certain areas within the recommended formation had been authorized to be developed by infill drilling prior to the date the tight formation recommendation was made and that certain drilling units within the area had been substantially developed by infill drilling without the incentive price. The Commission determined that 46 percent of thirteen drilling units contained three or more wells and 62 percent of those units contained two or more wells. Absent infill drilling authorization, only one well per drilling unit would have been permitted under applicable state spacing rules. Since the evidence showed that certain sections had been substantially developed by infill drilling, the Commission excluded those sections from designation as tight formations.

As previously noted, there are no well spacing rules applicable to the Dakota Group or Frontier formation due to their location on an Indian reservation. However, assuming that state spacing rules were applicable and that infill drilling had been authorized, the evidence demonstrates that no infill drilling had occurred at the time BLM's recommendation was made. Support for this conclusion is provided by information supplied by ARCO, accepted by BLM, and adopted by the Commission in Order No. 338, demonstrating that not more than one well per drilling unit had been completed in any of the subject formations as of the date of the recommendation.[11] Accordingly, application of the test set forth in Order No. 148 to the facts of this case leads to the conclusion that the subject formations had not been substantially developed.

Finally, MDU renews its contention that the record lacks substantial evidence in support of the need for an incentive price given the production history of the subject acreage. In Order No. 99,[12] the Commission made a generic finding that an incentive price is necessary under NGPA section 107(b), and thus is available to producers of gas from tight formations under section 107(c), provided the formation meets the standards set forth in the regulations, and provided that the producer is authorized by contract to collect the incentive rate. The Commission reaffirms its prior conclusion on this issue and declines to attempt to determine the need for incentive prices in individual cases where the applicable generic standards are satisfied.

Conclusion

The Commission concludes that the recommendation of BLM, as adopted by the Commission in Order No. 338, is supported by substantial evidence. The issues raised by MDU were considered by the Commission in Order No. 338 and have been reconsidered in this order. MDU has presented no facts or principles of law which would warrant modifying Order No. 338, reopening the record, or remanding the proceeding to BLM. MDU's request for rehearing and its petition to reopen and remand are accordingly denied. By the Commission.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 85-26970 Filed 11-12-85; 8:45 am]

BILLING CODE 6717-01-M

[10] 46 FR 29699 (June 3, 1981).

[11] *See* BLM Docket No. W-353-2 and W-354-2, ARCO Exhibit Nos. 1 and 2. This fact is acknowledged by MDU in its comments filed on June 14, 1984. (MDU states only that the subject drilling units contain "at least" one well. It does not allege that any drilling unit contains more than one well. Exhibit No. 2 of Appendix A to MDU's comments shows that, in fact, none of the drilling units contained more than one well as of the date of BLM's recommendation).

[12] 45 FR 56034 (Aug. 22, 1980).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Social Security Administration

20 CFR Part 416

42 CFR Part 435

Medicaid and Supplemental Security Income; Eligibility to Severely Impaired Individuals Who Perform Substantial Gainful Activity

AGENCY: Social Security Administration and Health Care Financing Administration, HHS.

ACTION: Final rule.

SUMMARY: These regulations reflect the amendment to section 201(d) of Pub. L. 96-265 made by section 14(a) of Pub. L. 98-460, the Social Security Disability Benefits Reform Act of 1984. Section 201(d) provided that the provisions of section 201 (a) and (b) of Pub. L. 96-265 were effective January 1, 1981, through December 31, 1983; section 14(a) of Pub. L. 98-460 simply extended the expiration date, without other modification, from December 31, 1983 to June 30, 1987. Sections 201 (a) and (b) provide for the continuation of Supplemental Security Income (SSI) benefits and eligibility for Medicaid for certain severely impaired SSI recipients who work and engage in substantial gainful activity (SGA), and for retaining eligibility status for Medicaid for certain of these recipients who become ineligible for SSI benefits because of their earnings. They also provide that States which elect to do so may augment these benefits with State supplementary payments.

DATES: These rules are being issued as final regulations and they are effective on November 13, 1985. The statutory change they implement was enacted on October 9, 1984 and made retroactive to January 1, 1984.

FOR FURTHER INFORMATION CONTACT:

For SSI Provisions: Fred Miranda, Legal Assistant, Office of Regulation, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone (301) 594-7341.

For Medicaid Provisions: Marinos Svolos, Director, Division of Medicaid Eligibililty Policy, Health Care Financing Administration, 6325 Security Boulevard, Baltimore, Maryland 21207, telephone (301) 594-9050.

SUPPLEMENTARY INFORMATION: The purpose of these final regulations is to

reflect the amendment of section 201(d) of Pub. L. 96–265 by section 14(a) of Pub. L. 98–460, the Social Security Disability Benefits Reform Act of 1984. Section 201(d), when it was enacted as a provision of the Social Security Disability Amendments of 1980 (Pub. L. 96–265), provided that the provisions of sections 201 (a) and (b) of that Act were effective January 1, 1981 through December 31, 1983. Section 14(a) of Pub. L. 98–460 extended this effective period through June 30, 1987.

Section 201 was one of the several work incentive provisions included in Pub. L. 96–265. It established a 3-year demonstration project under section 1619 of the Act (hereafter referred to as the 1619 demonstration project). The 1619 demonstration project provided that certain individuals with disabling impairments, who lost their eligibility for regular SSI benefits based on disability, could become eligible for special cash benefits and retain eligibility for Medicaid. Further, certain of these individuals who, because of their earnings, became ineligible for SSI cash benefits (including special benefits) could still retain eligibility status for Medicaid. The special cash benefits payable under the 1619 demonstration project are computed in the same way as regular SSI benefits payable to recipients who are disabled. Also, States which elected to do so could augment the special benefits with State supplementary payments.

The expectation, when section 1619 was enacted, was that information would be gathered regarding the characteristics of those who benefit from section 1619 and the impact of such a program on reducing work disincentives for the disabled. A major reason that section 1619 was extended was to enable us to collect additional and more complete data on the effects of the provision.

The amendment extending the section 1619 program also directed us, in cooperation with the Department of Education, to develop and disseminate information and establish training programs for staff personnel, regarding the potential availability of benefits and services under the provisions of section 1619. This mandate was motivated by congressional concern that, unless we made a greatly increased effort to get information out to a broad range of individuals and organizations, many disabled individuals would not be made aware of this congressional attempt to eliminate the work disincentives for those disabled individuals who are able and who wish to work despite their impairment.

In late 1983, neither the Social Security Administration nor the Health Care Financing Administration had been able to compile enough data to determine effectively whether permitting work by severely impaired recipients while continuing their SSI benefits and/or Medicaid eligibility status acted as an incentive for these recipients to begin or continue working. Consequently, on March 15, 1984, we announced in the **Federal Register** (at 49 FR 9774) the establishment of the demonstration project under section 1110 of the Act (hereafter the 1110 demonstration project) which used the criteria of the 1619 demonstration project that had expired on December 31, 1983. The 1110 demonstration project was to also have the purpose of testing whether providing extended assistance encouraged work efforts. This project was to remain in effect for the 1984 calendar year—expiring on December 31, 1984. This project was superseded by the provisions of section 14(a) of Pub. L. 98–460, which were retroactive to January 1, 1984, the effective date of the 1110 demonstration project.

Provisions of Section 14 of Pub. L. 98–460

Section 14(a) of Pub. L. 98–460 amended section 201(d) of Pub. L. 96–265 by providing that the provisions of sections 201 (a) and (b) of the statute would remain in effect through June 30, 1987, rather than only through December 31, 1983. Those sections, as discussed above, authorized the work incentive demonstration project under section 1619 of the Act that was effective for the period January 1, 1981, through December 31, 1983.

Under section 1619(a) of the Act, an individual with a disabling impairment who lost his or her SSI benefits because he or she performed work demonstrating the ability to engage in substantial gainful activity (SGA) could become eligible for special SSI cash benefits. These special benefits under section 1619(a) were computed in the same way as the SSI benefits which were paid to aged, blind and disabled SSI recipients. In addition, they could be augmented by State supplementary payments if a State elected to do so.

An individual qualified for special SSI cash benefits under section 1619(a) if—

(1) In the month before the month for which eligibility was being determined he or she was eligible for regular SSI benefits or special SSI cash benefits under section 1619(a) or federally administered State supplementary payments; and

(2) In the month for which eligibility was being determined he or she has a disabling physical or mental impairment, but, because he or she had engaged in SGA, he or she was not eligible for regular SSI benefits based on disability.

An individual who received special SSI cash benefits under section 1619(a) maintained his or her eligibility for Medicaid in a State in which he or she was eligible as an SSI recipient. A recipient with income which include earnings that reduced his or her Federal SSI benefits to zero also lost his or her eligibility for the special SSI cash benefits under section 1619(a) but could retain Medicaid eligibility. Under section 1619(b) of the Act, a beneficiary who was a severely impaired or blind individual (under age 65) and who was eligible for regular SSI benefits, special SSI cash benefits under section 1619(a) or State supplementary payments in the month before the first month for which eligibility is being determined, could acquire a special SSI eligibility status for purposes of Medicaid services if he or she met certain conditions. These conditions were that he or she: (1) Continued to be blind or to have disabling impairment; (2) would be eligible for cash benefits but for these earnings; (3) would be seriously hindered from working if he or she lost Medicaid coverage; and (4) did not have earnings from work that were reasonably equivalent to the total of SSI benefits, State supplementary payments and Medicaid that he or she would have received but for these earnings.

Regulatory Provisions

We are amending §§ 416.260, 416.261 and 416.1332 of our regulations to reflect the amendment to section 201(d) of Pub. L. 96.265 made by section 14(a) of Pub. L. 98.460. Current section 416.260, as the introductory section to §§ 416.261 through 416.269, briefly outlines the demonstration project that was established under section 1619 of the Act by section 201 of Pub. L. 96–265. This section explains that for the 3-year period beginning January 1, 1981 and ending December 31, 1983, a person who works despite a disabling impairment may qualify for special SSI cash benefits as well as for Medicaid when his or her earnings exceed the established SGA limits described in § 416.974(b) of our rules. It also points out that for purposes of determining eligibility or continuing eligibility for Medicaid during this period, a blind or medically impaired person (no longer eligible for SSI), who except for earnings would otherwise be eligible for SSI benefits, may be eligible for an SSI eligibility status under which he or she is considered a blind or

disabled individual receiving SSI benefits. Section 416.260 as amended provides that the period for which the special SSI cash benefits may be provided and during which the special SSI eligibility status can be acquired has been extended through June 30, 1987.

Section 416.261 of our rules, which discusses the nature of the special SSI cash benefits and when they are payable, has been amended in a manner similar to that in which § 416.260 has been amended. Section 416.261 as amended, provides that special SSI cash benefits are benefits that may be paid for months through June 30, 1987, to an individual who is not otherwise eligible for regular SSI benefits because he or she demonstrates the ability to engage in SGA. Prior to this change in our rules, § 416.261 provided that these special SSI cash benefits could be paid only for months from January 1, 1981 through December 31, 1983.

Section 416.1332 of our rules currently provide that if you are no longer eligible for regular SSI benefits because you demonstrate that you are able to engage in SGA, you can qualify for special SSI cash benefits in the period January 1, 1981 through December 31, 1983 if you meet the eligibility requirements discussed in § 416.262. Section 416.1332 as amended, provides that you now can qualify for the special SSI cash benefits through June 30, 1987.

Related Amendment to Medicaid Regulations

Section 14(a) of Pub. L. 98–460 extends the provision under section 1619 of the Social Security Act that permits certain severely impaired individuals who receive a special payment under SSI (despite monthly earnings that exceed the limits for SGA) to retain Medicaid eligibility until June 30, 1987. The section 1619 provision for Medicaid coverage previously was in effect from January 1, 1981 until December 31, 1983. We have amended the regulations governing Medicaid eligibility groups at 42 CFR 435.120 to reflect the extension of time for this provision.

Effective Dates

The statutory amendment extending the period during which we may continue special SSI benefits and/or eligibility for Medicaid under section 1619 for certain severely impaired SSI recipients who work and engage in substantial gainful activity was enacted October 9, 1984, and made retroactive to January 1, 1984. The SSI regulations are effective November 13, 1985.

The Medicaid regulations under § 435.120(a)(3) are effective on November 13, 1985 and apply to SSI eligibility determinations made under section 1619(b) of the Social Security Act through June 30, 1987.

Final Rule

The Department, even when not required by statute, as a matter of policy, generally follows the Administrative Procedure Act (APA) Notice of Proposed Rulemaking and public comment procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that under 5 U.S.C. 553(b)(B), good cause exists for waiver of notice of proposed rulemaking and public comment procedures on this regulation since opportunity for public comment is unncessary in this case because the statutory provision upon which the regulations are based simply extends the effective date of section 1619 and allows for no discretion. Therefore, these rules are being issued as final rules and will become effective on the date they are published in the **Federal Register**.

Regulatory Procedures

Executive Order 12291

These regulations have been reviewed under Executive Order 12291 and do not meet any of the criteria for a major rule because they will not have an annual effect on the economy of $100 million or more and will not cause increases in costs or prices. Therefore, a regulatory impact analysis is not required.

Fiscal SSI program savings are estimated as $5.6 million annually, whereas estimated Medicaid program costs are $1.1 million for FY 85 and $1.2 million for FY 86. Thus, the estimated net program savings are $4.5 million for FY 85 and $4.4 million for FY 86. In addition, fiscal nonprogram or administrative expenses are $420,000 annually. This includes a $60,000 increase in costs that is directly attributable to the enactment of section 14(a) of Pub. L. 98–460.

Paperwork Reduction Act of 1980

These reductions impose no additional reporting and recordkeeping requirement requiring Office of Management and Budget clearance under the requirements of the Paperwork Reduction Act.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only States and a limited number of individuals. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96–354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 13.714—Medical Assistance and Program No. 13.807, Supplemental Security Income Program)

List of Subjects

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income (SSI).

42 CFR Part 435

Aid to Families with Dependent Children, Aliens, Categorically needy, Contracts (Agreements—State Plan), Eligibility, Grant-in-Aid, program—health, Health Facilities, Medicaid, Medically needy, Reporting requirements, Spend-down, Supplemental Security Income (SSI).

Dated: June 13, 1985.

Martha A. McSteen,

Acting Commissioner of Social Security.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: November 6, 1985.

Margaret M. Heckler,

Secretary of Health and Human Services.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Part 416 of Title 20 of the Code of Federal Regulations is amended as follows:

Subpart B—Eligibility

1. The authority citation for §§ 416.261 through 416.266 of Subpart B of Part 416 is revised to read as follows:

Authority: Secs. 1102, 1611, 1616, 1618, 1619, 1631, and 1634 Social Security Act as amended, sec. 212 of Pub. L. 93–66, as amended; 49 Stat. 647, as amended, 86 Stat. 1466, 1474, 1475, and 1478, 90 Stat. 2901, 87 Stat. 155, and 94 Stat. 445, 42 U.S.C. 1302, 1382e, 1382g, 1383, 1383c, 1382h and 1396, sec. 14(a) of Pub. L. 98–460, 98 Stat. 1808.

§ 416.260 [Amended]

2. In § 416.260, the second sentence is revised by removing the words "for a 3-year period beginning January 1, 1981, and ending December 31, 1983." and adding the words "for the period beginning January 1, 1981, and ending June 30, 1987" in lieu thereof.

§ 416.261 [Amended]

3. In § 416.261, the first sentence is revised by removing the words "through December 31, 1983," and adding the words "through June 30, 1987" in lieu thereof.

Subpart M—Suspensions and Terminations

4. The authority citation for Subpart M is revised to read as follows:

Authority: Secs. 1102, 1611–1615, and 1631 Social Security Act, as amended, 49 Stat. 647, as amended, 86 Stat. 1466–1477, (42 U.S.C. 1302, 1382–1382d, 1383), sec. 14(a) of Pub. L. 96–460, 98 Stat. 1808 unless otherwise noted.

§ 416.1332 [Amended]

5. In § 416.1332, the first sentence is revised by removing the words "in the period January 1, 1981 through December 31, 1983" and adding the words "for the period beginning January 1, 1981, and ending June 30, 1987".

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, AND THE NORTHERN MARIANA ISLANDS

Part 435 of Title 42 of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. The introductory text of § 435.120(a) is reprinted and paragraph (a)(3) is revised to read as follows:

§ 435.120 Individuals receiving SSI.

(a) *General provisions.* Except as allowed under § 435.121, the agency must provide Medicaid to aged, blind, and disabled individuals or couples who receive SSI, including—

* * * * *

(3) For the period beginning January 1, 1981, and ending June 30, 1987, individuals considered to be receiving SSI under section 1619(b) of the Act (blind individuals or those with disabling impairments whose income equals or exceeds a specific Supplemental Security Income limit). (Regulations at 20 CFR 416.263 through 416.269 contain requirements governing determinations of eligibility under this provision.)

* * * * *

[FR Doc. 85–26941 Filed 11–12–85; 8:45 am]

BILLING CODE 4190–11–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 251

[Docket No. R–85–1259; FR–2143]

Technical Rule To Clarify Labor Standards Responsibilities in Connection With Coinsurance of Multifamily Housing Projects; Announcement of Effective Date

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

ACTION: Notice of announcement of effective date for final rule.

SUMMARY: This notice announces the effective date for the final rule published in the **Federal Register**, on October 2, 1985 (50 FR 40195), that clarified Part 251 to indicate that the Federal Housing Commissioner retains responsibility for enforcement of labor standards and prevailing wage requirements. It also delegated to the coinsuring lender only routine administration and enforcement functions, subject to monitoring by the Commissioner.

The effective date provision of the rule stated that the rule would become effective upon expiration of the first period of 30 calendar days of continuous session of Congress after publication, and announced that future notice of the effectiveness of the rule would be published in the **Federal Register.**

Thirty calendar days of continuous session of Congress have expired since the rule was published.

DATE: The effective date for the final rule published October 2, 1985 (50 FR 40195), is November 5, 1985.

FOR FURTHER INFORMATION CONTACT: James Hamernick, Office of Multifamily Housing Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 6132, Washington, D.C. 20410, telephone (202) 755–6500. (This is not a toll-free number.)

Dated: November 6, 1985.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 85–26908 Filed 11–12–85; 8:45 am]

BILLING CODE 4210–27–M

VETERANS ADMINISTRATION

38 CFR Part 21

Veterans Education; Delegation of Authority

AGENCY: Veterans Administration.

ACTION: Final Regulations.

SUMMARY: A discrepancy exists between two VA regulations as to who has authority to approve special restorative training of more than 12 months for children entitled to dependents' educational assistance. One of those regulations is amended to bring it into agreement with the other. The Director, Vocational Rehabilitation and Counseling Servcie is delegated the authority to make these decisions.

EFFECTIVE DATE: November 5, 1985.

FOR FURTHER INFORMATION CONTACT: June C. Schaeffer (225), Assistant Director for Policy and Program Administration, Education Service, Department of Veterans Benefits, Veterans Administration, 810 Vermont Avenue NW., Washington, D.C. 20420 (202) 389–2092.

SUPPLEMENTARY INFORMATION: On pages 23145 and 23146 of the **Federal Register** of May 31, 1985 there was published a notice of intent to amend Part 21 to bring into agreement the two regulations which govern who has authority to approve special restorative training of more than 12 months for children entitled to dependents' educational assistance.

Interested people were given 30 days to submit comments, suggestions, or objections. The VA (Veterans Administration) received one letter from an educational organization.

The letter stated that there was no objection to the proposal. Accordingly, the VA is making the proposal final without change.

This amended regulation affects only internal VA management. Therefore, it is not subject to E.O. 12291, entitled Federal Regulation.

The Administrator of Veterans' Affairs has certified that this amended regulation will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA). Under 5 U.S.C. 605(b), this regulation, therefore, is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

This certification can be made because this amended regulation affects only internal VA management. The regulation will have no significant

impact on small entities, i.e., small businesses, small private and nonprofit organizations, and small governmental jurisdictions.

The Catalog of Federal Domestic Assistance number for the program affected by this regulation is 64.117.

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

By direction of the Administrator.

Approved: November 5, 1985.

Everett Alvarez, Jr.,

Deputy Administrator.

PART 21—[AMENDED]

38 CFR Part 21, Vocational Rehabilitation and Education, is amended by revising § 21.4001(c)(3), and by adding paragraph (g) so that the revised and added material reads as follows:

§ 21.4001 Delegations of authority.

* * * * *

(c) * * *

(3) Approval of courses under § 21.4250(c)(2).

(38 U.S.C. 212(c))

* * * * *

(g) Authority is delegated to the Director, Vocational Rehabilitation and Counseling Service to exercise the functions required of the Administrator for approval of courses under § 21.4250(c)(1).

(38 U.S.C. 212(a))

[FR Doc. 85-26968 Filed 11-12-85; 8:45 am]

BILLING CODE 8320-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 158 and 162

[OPP-30078A; FRL #2859-9]

Product Performance Requirements for Vertebrate Control Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule amends EPA's pesticide registration data requirements to reinstate a requirement for the submission of efficacy data for certain vertebrate control products. At the same time, EPA is revising its conditional registration regulations to rescind an efficacy data waiver that would be inconsistent with the new requirement. Applicants for registration of such products must submit or cite to the Agency efficacy data to support the registration of each pesticide product that claims to control vertebrates having human health implications. EPA uses the information to make regulatory judgments with respect to the efficacy of each vertebrate control product proposed for registration or experimental use.

EFFECTIVE DATE: This rule will become effective after 60 calendar days of continuous Congressional session following the date of promulgation. EPA will issue a notice in the **Federal Register** stating the actual effective date of the rule.

FOR FURTHER INFORMATION CONTACT: By mail: Bernard A. Schneider, Benefits and Use Division (TS-768C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Office location and telephone number: Rm. 705, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-2161).

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the sale and distribution of pesticide products, in part by a pre-market registration scheme. To obtain registration, an applicant must demonstrate to the Agency (by submitting or citing data) that the product will not cause (or significantly increase the risk of) unreasonable adverse effects on man and the environment.

EPA issued a final rule concerning pesticide data requirements (40 CFR Part 158), which was published in the **Federal Register** of October 24, 1984 (49 FR 42856). That final rule listed the data requirements applicable to pesticide products, including efficacy data for certain products that are intended to control pests of public health significance. In that final rule, the Agency announced its intention of adding a requirement for efficacy data for vertebrate control products intended for the control of pests that directly or indirectly transmit disease to humans. The Agency decided to take this action based on comments received on its proposal, which had not included vertebrate efficacy data requirements. A significant number of commenters had urged that the Agency include these requirements in its final rule.

The efficacy data requirement for vertebrate control products would have been included in Part 158 at the time of its October 1984 promulgation but for the fact that another regulation contained in 40 CFR 162.163 waived the submission of efficacy data for such products. Section 162.163 provides a general waiver of efficacy data submission for all products unless specifically stated otherwise. Currently only microorganisms infectious to man in the inanimate environment and toxin-producing fungi are specifically listed. To promulgate a requirement for vertebrate efficacy data submission while elsewhere waiving such submission would have created an inconsistency in Agency regulations that could have been confusing to pesticide applicants and registrants.

Therefore, the Agency subsequently proposed to revise § 162.163 to eliminate the inconsistency by rescinding the general waiver with respect to vertebrate control products. That proposal was published in the **Federal Register** of September 12, 1984 (49 FR 35804). This final rule accomplishes both the rescission of the efficacy data waiver in § 162.163 and the inclusion of efficacy data requirements for certain vertebrate control products in § 158.160.

II. Comments Received

In response to the Agency's proposal of pesticide data requirements (Part 158) that excluded efficacy data for vertebrate control products, the Agency received a total of 20 comments, all but 1 of which opposed granting a waiver of efficacy data submission for public health products, including vertebrate control products. Commenters cited various reasons for opposing a waiver of efficacy data:

1. The marketplace does not work to regulate inefficacious products as rapidly or as effectively as claimed by the Agency in proposing the waiver.

2. A waiver of data will lead to increased numbers of inefficacious products marketed by "fly-by-night" companies at the expense of reliable companies.

3. States do not have sufficient authority or funding to regulate efficacy, and do not have facilities for independently evaluating efficacy of pesticide products.

These comments were reinforced by Agency scientists' concerns over apparent lack of efficacy of a number of vertebrate control products already on the market. The reasons for the Agency's decision to inlcude an efficacy data requirement for vertebrate control products were discussed further in the September 12, 1984, proposal to rescind the waiver.

Three comments were received on the Agency's proposed rescission of the efficacy data waiver for vertebrate control products. Two commenters supported the proposed inclusion of efficacy data requirements, essentially for the same reasons that earlier commenters opposed the waiver. The other commenter, while not expressly opposing rescission, posed a number of questions concerning efficacy data for vertebrate control products.

This commenter asked whether efficacy testing encompassed field testing. Requirements for product performance data on rodenticides and other vertebrate control products are specified in 40 CFR 158.160 (as amended by this final rule). That section refers to Subdivision G of the Pesticide Assessment Guidelines, which contains recommended test methodology for determining the efficacy of pesticide products.[1] Briefly, the requirements specify three series of tests for each active ingredient in a commensal rodenticide:

1. Acute and subacute toxicity studies, which are used to establish the toxicity of the rodenticide to potential target species and to aid in estimating appropriate active ingredient concentrations in the finished product.

2. Laboratory efficacy studies, which are used to detemine whether the target species will ingest the active ingredient under conditions in which they are provided an alternative to ingestion.

3. Field efficacy studies to determine whether successful control can be achieved under conditions of actual use.

Once the efficacy of an ingredient is established under field conditions, subsequent products containing the same concentration of that active ingredient may be registered by submitting data from laboratory testing demonstrating that the new product meets the criteria for potency and palatability to the target species, and by citing the prior field study.

In a second question, the commenter asked whether all registrants of commensal rodenticides would be required to submit field test studies for products that are currently registered, or, on the other hand, whether products already on the market would be removed from the market until test data are provided. Applicants for new registration of commensal rodenticide products will be required to submit or cite the data mentioned above. The data required by 40 CFR 158.160 will be routinely required for new products.

The Agency, however, will not take steps to remove an already-registered product from the market simply because the Agency has concluded that it needs additional efficacy data. If the Agency determines that efficacy data of the types mentioned are necessary to evaluate currently registered products, EPA will require that registrants submit such data. FIFRA sec. 3(c)(2)(B) provides that the Agency may require, under penalty of suspension of registration, that any data needed to maintain registration of a product or active ingredient be submitted by its registrants.

Finally, the commenter stated that requiring current registrants to meet the efficacy standard required of new products would have a significant impact on a substantial number of small entities. The Agency has determined that the cost of the initial field study is approximately $6,500, and that the costs of the supplementary laboratory studies for a new product containing an active ingredient which is contained in currently registered products would be in the range of $1,200–$3,500. This cost would be lower if conducted by the registrant in his own testing facility. EPA does not consider this cost to be significant, nor to have a significant impact on small businesses.

III. Regulatory and Statutory Review Requirements

In accordance with FIFRA sec. 25(a), copies of this final rule were provided to the FIFRA Scientific Advisory Panel, the Secretary of Agriculture, and Congressional Committees. No comments were received from the Secretary of Agriculture or the Congressional Committees. The Scientific Advisory Panel waived its review of this final rule.

Under E.O. 12291, the Agency must determine whether a rule is "major" and therefore requires a Regulatory Impact Analysis. The impacts or requiring efficacy data on vertebrate control products have been evaluated in conjunction with the issuance of Part 158, for which a comprehensive Regulatory Impact Analysis was conducted. Based on that analysis, the Agency has determined that:

1. This rule is not a "major" rule as defined by Executive Order 12291. This rule has been submitted to the Office of Management and Budget (OMB) for approval as required by Executive Order 12291.

2. This rule will not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 60 *et seq.*); therefore, a separate Regulatory Flexibility Analysis is not required.

3. The information collection requirements contained in this rule have been approved by the OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned the OMB control numbers: 2070–0060 (Registration of Pesticides under section 3 of FIFRA), and 2070–0057 (Data Call-In/ Registration Standards Program).

List of Subjects in 40 CFR Parts 158 and 162

Administrative practice and procedure, Pesticides and pests, Data requirements, Intergovermental relations, Packaging and containers, Labeling.

Dated: October 30, 1985.

Lee M. Thomas,

Administrator.

Therefore, Title 40, Chapter I, is amended as follows:

PART 158—[AMENDED]

1. The authority citation for Part 158 is revised to read as follows:

Authority: 7 U.S.C. 136 et seq.

2. In § 158.160, by revising the "Efficacy of Vertebrate Control Agents" under paragraph (a) and removing and reserving paragraph (b)(2), to read as follows. Paragraph (b) is shown for the convenience of the reader and remains unchanged.

§ 158.160 Product performance data requirements.

(a) Table. * * *

[1] The Pesticide Assessment Guidelines are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA. 22161.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
*		*		*		*		*		*			
Efficacy of Vertebrate Control Agents													
Avian toxicants	(1)	(R)	(R)						(R)	(R)		EP*	96-5
Avian repellents	(1)	(R)	(R)						(R)			EP*	96-6
Avian frightening agents	(1)	(R)	(R)						(R)			EP*	96-7
Bat toxicants and repellents.	(1)									(R)		EP*	96-9
Commensal rodenticides	(1)	(R)	(R)						(R)	(R)	TEP	EP*	96-10
Rodenticides on farm and rangelands.	(1)	(R)	(R)						(R)			EP*	96-12
Rodent fumigants	(1)	(R)	(R)						(R)	(R)		EP*	96-13
Rodent reproductive inhibitors.	(1)	(R)	(R)						(R)	(R)		EP*	96-16
Mammalian predacides	(1)	(R)	(R)						(R)			EP*	96-17
*		*		*		*		*		*			

(b) Notes. The following notes are referenced in column two of the table contained in paragraph (a) of this section.
(1) The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.
(2) [Reserved].

PART 162—[AMENDED]

3. By revising § 162.163(b)(2) and adding OMB Control Number 2070–0060 at the end of the section to read as follows:

§ 162.163 Data required for agency review of applications for conditional registration.

* * * * *

(b)* * *

(2) *Efficacy data.* (i) Efficacy data for each product to the extent required by 40 CFR 158.160; and

(ii) Efficacy data for each product for which a new or added use is proposed, if the product contains an active ingredient, some uses of which have been suspended, cancelled, or are the subject of a notice issued under § 162.11(a)(3)(ii), and the risks identified in the notice or suspension/cancellation action may reasonably be anticipated as a result of the new use.

* * * * *

[Approved by the Office of Management and Budget under Control Number 2070–0060.]

[FR Doc. 85–26940 Filed 11–12–85; 8:45 am]
BILLING CODE 6560–50–M

40 CFR Part 717

[OPTS–83001F; TSH FRL 2895–3]

Records and Reports of Allegations of Significant Adverse Reactions to Health or the Environment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule amends two provisions of the rule that implements section 8(c) of the Toxic Substances Control Act (TSCA). The first amendment states that the "coincidental manufacture" of a chemical substance by itself is not an act that makes a person subject to the rule. A second amendment modifies the language regarding which chemical processors are subject to the rule. This rule also answers questions regarding the relationship of section 8(c) to section 8(e) and who is responsible for 8(c) recordkeeping when a subsidiary is owned equally by two parent companies.

DATES: In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern daylight time on December 27, 1985. This rule shall become effective on November 27, 1985.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543, 401 M St., SW., Washington, D.C. 20460, Toll free: (800–424–9065), In Washington, D.C.: (554–1404), Outside the USA: (Operator—202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Background

EPA issued a final regulation implementing section 8(c) of TSCA which was published in the **Federal Register** of August 22, 1983 (48 FR 38178). This rule became effective on November 21, 1983. The rule requires manufacturers and certain processors of chemical substances and mixtures to keep records of "significant adverse reactions" alleged to have been caused by such substances or mixtures. After promulgation, the Agency determined that it needed to clarify certain provisions of the rule based upon questions and other communications. EPA proposed amendments to the rule which were published in the **Federal Register** of December 24, 1984 (49 FR 49865). That notice proposed two basic amendments to the rule.

One of the proposed amendments involved exempting persons whose sole "manufacturing" activity involved the coincidental production of chemical substances. The American Paper Institute (API) brought it to the Agency's attention that such an exemption should have been included in the final rule. Similar provisions are included in the TSCA Inventory Regulations and the Premanufacture Notification (PMN) rules. The Agency agreed with API to the extent that the lack of such a coincidental manufacturer exemption was a technical oversight in the preparation of the final section 8(c) rule. EPA considered issuing a statement of intent not to enforce the rule with respect to such "manufacturers." However, Agency staff determined that the most appropriate method was to propose an amendment to the section 8(c) rule specifically exempting such persons. The proposed exemption was intended to apply to persons—not to allegations about coincidentally produced substances. As part of this action, language was proposed to be added to the rule under paragraphs that outline what allegations a manufacturer or processor must keep. This language was intended to close any potential gap that would have prevented recordkeeping of allegations relating to coincidentally produced substances.

The other proposed amendment was intended to clarify which chemical processors are subject to the rule. The rule cites the Standard Industrial

Classification (SIC) codes 28 and 2911 to delimit the processors that the Agency determined should be required to keep records under this rule. However, the language "engaged in activities described" in these SIC codes was criticized as being too vague. Therefore, the proposed amendment modified the language and put the emphasis on a company's end products being of a type described in these SIC codes.

The proposal notice also presented clarifying remarks, all related to sections of the rule that specify who is and who is not subject to the rule's requirements.

II. Discussion of Comments

EPA received comments from the following organizations: Chemical Manufacturers Association, Chemical Specialties Manufacturers Association, Environmental Defense Fund, General Electric Company, National Paints and Coatings Association, and the Dow Chemical Company. Although none were received by the comment deadline of February 22, 1985, the Agency fully considered all of these comments.

In general, the Chemical Specialties Manufacturers Association, the Chemical Manufacturers Association, and the National Paints and Coatings Association agreed with the two proposed amendments. However, other comments disagreed with EPA on certain points of the proposed amendments and additional questions were raised regarding the 8(c) rule.

Therefore, this unit contains three subunits. Two of the subunits outline comments on the two proposed amendments and give EPA's response. A third subunit deals with additional questions.

A. Amendment To Exempt Concidental Manufacturers

Comments. The Environmental Defense Fund (EDF) objected to the proposal of a coincidental manufacturer exemption. EDF contends that the amendment is not consistent with the general intent of section 8(c) to generate information related to toxic effects of chemical substances and that no overriding public interest is served by such restriction. EDF disagreed that the proposed amendment was consistent with the rule's promotion of product stewardship, i.e. that the producer rather than the user of a chemical product should be responsible for keeping allegations records. They state that such assumed responsibility can be exeedingly burdensome and complex and that it is highly unlikely that the original producer could, with the best of intentions, maintain adequate surveillance of all persons involved in the life history of a product. EDF also expressed the opinion that the proposed exemption of coincidental manufacturers was developed with inadequate attention to possible situations in which adverse effects could result from coincidental generation of hazardous substances. An example cited is the depolymerization of chemical substances during high temperature molding processes with subsequent generation of toxic monomers. EDF contends that with the adoption of a coincidental manufacturer exemption such persons "would be under no obligation to report any adverse effects," presumably to EPA.

The Dow Chemical Company (Dow) objected to part of the proposed coincidental manufacturer exemption. Dow's basic contention is that the user of their product should keep allegations relating to coincidental generation of substances during such use or disposal.

As Dow states it, coincidental manufacture of chemicals may occur several steps in the marketing chain away from the original manufacturer or processor and may involve more than one supplier at any step. Of special concern to Dow is the problem of coincidental manufacture occurring after mixture with one or more additional substances. It is especially when such multi-component systems exist that Dow argues for section 8(c) recordkeeping by the location most closely associated with the production of the reaction product. Dow asserts that the goals of section 8(c) would be better served if the customer, user, or disposer kept allegation records and were able to discern patterns of complaints which could be associated with a given supplier over a period of time.

EPA's response. As stated in Unit I, EPA views the coincidental manufacturer exemption as basically a technical amendment. EPA never intended to require such "coincidental manufacturers" to keep records. The absence of such exemption language in the final rule was an inadvertent omission on the Agency's part. Therefore, EPA disagrees with EDF's characterization of the amendment as a "restriction."

By not specifically exempting such manufacturers both EDF and Dow are asking EPA to apply the section 8(c) rule to potentially hundreds of thousands of users of chemical substances. Such action would totally reverse the rule's emphasis of focusing the recordkeeping responsibility on those who are primarily responsible for making and distributing chemical products in U.S. commerce.

EPA contends that this "sole" coincidental manufacturer exemption is consistent with the current rule because it maintains this concentration philosophy.

The product stewardship reference in the proposed amendment may have been misinterpreted by EDF. EPA intends that subject manufacturers or processors monitor closely their own corporate activities. In addition they should make a reasonable attempt to request that their customers forward to them potentially recordable allegations about their products. One basic assumption of the rule is that market forces will act to create a passback of allegations from non-subject processors/users of chemicals. In other words a subject company's own economic self interest is served by having a positive desire to find out if customers are experiencing problems with a product and why. Such a problem could be the undesirable "coincidental" generating of a toxic agent upon the intended end use of their product. EPA's contention is that product stewardship and a non-mandatory allegation passback mechanism will funnel these types of complaints or allegations to a party that has some responsibility for placing the product in commerce. It is therefore neither necessary nor practical to make the entire universe of chemical users subject to recordkeeping responsibilities of the rule.

The Agency recognizes that substances can be and are produced coincidentally during further processing, use, and disposal. This amendment does not in any way exempt from recordkeeping allegations citing a coincidentally produced substance. Again, the exemption targets "persons", not allegations that may cite a coincidentally produced substance. This is why the amendment contains language specifically stating that a subject manufacturer or processor has to collect allegations citing a substance produced coincidentally as a result of further processing, use, or disposal of that subject company's product. Otherwise, a company could refuse to record an allegation that cites a substance (the coincidentally produced substance) it does not specifically make.

EPA's basic contention is that if a company distributes a product in commerce that will, upon intended end use, produce potentially harmful byproducts, then it is incumbent upon that company, at a miminum, to record such allegations along with any other allegations that may directly cite the product as the cause of a significant adverse reaction. Dow's argument that

they should not be the keeper of such records seems no different from similar arguments put forward in comments on the initial section 8(c) rule. EPA's opinion is that the long-term advantages of being made aware of unexpected coincidental generation problems outweigh any perceived disadvantages of burden or liability associated with recording such allegations.

B. Amendment To Clarify Which Processors Are Subject

Comments. Dow, in general, objected to the use of SIC codes as a means of defining which processors are subject to the rule. Dow contends that "establishments" and not products are described in the SIC Major Groups. Dow states that the products listed in the SIC manual are intended only as illustrations to describe the results of activities which are listed within a SIC major group. Dow concludes that the proposed language attempts to alter the intended use of the SIC manual. Dow recommends two alternatives to the proposed amendment. One approach would have EPA actually list in the regulation all the products covered by the SIC 28 and 2911 major groups without reference to the SIC manual. The other option would be to modify the rule language so that it would refer to SIC code 28 and 2911 establishments and not to the products that result from activities of these establishments. In Dow's words, there would be no confusion because operators of establishments have already determined if the establishment is within SIC major group 28 or 2911 for regulatory purposes.

General Electric Company (GE) also commented on the processor issue. GE stated that EPA's proposed amendment provided little in the way of clarification. GE also criticized the use of the SIC codes as a way of defining processors subject to the rule. In GE's words, requiring a company to wade through the SIC manual every time an allegation is made regarding a company product constitutes an undue and unreasonable burden. GE recommends a simplified method outlining who in total is subject to the 8(c) rule.

GE contends that the majority of the "processors" that EPA intends to cover are actually manufacturers of mixtures. The only exception according to GE would be the repackagers of chemical substances and mixtures. Therefore, GE recommends that in order to clarify which processors are subject to the section 8(c) rule, EPA should revise the regulatory language of § 717.5 to state that persons subject to the rule include all manufacturers of chemical substances and mixtures and all repackagers of chemical substances and mixtures.

EPA's response. In finalizing the section 8(c) rule, EPA sought to develop a way to limit and at the same time adequately specify which chemical processors would have recordkeeping responsibility. It was a situation similar to the coincidental manufacturer issue where literally hundreds of thousands of businesses could be considered chemical processors. The Agency had to provide the processor universe with some criteria for determining whether it is subject to the rule. Also, the Agency needed to be able to quantify these processors for purposes of rule burden estimation.

The Agency does not consider that it used the SIC code system inappropriately in the context of its implementation of section 8(c). As stated in the SIC manual, "Each establishment is assigned an industry code on the basis of its primary activity which is determined by its principal product or group of products produced or distributed, or services rendered." These code descriptions, including representative products, provide the measure by which a company classifies its establishments. In essence, they are what they do.

With regard to the options recommended by Dow, EPA does not consider the copying of the SIC products into the regulatory language to be an improvement over the proposed amendment. The SIC manual is a well known and readily available standard reference. Transcribing the product listings into the regulatory language will not further clarify which processors are subject to the rule or reduce the regulatory burden on industry. Dow's other recommendation to target the SIC establishments was considered by the Agency prior to proposal of the amendment. It would be a somewhat more simplified means of designating who is subject but, would be more restrictive in its coverage than the Agency believes appropriate in implementing section 8(c). The SIC code refers to an establishment's "primary" activity. By adopting Dow's approach, EPA would lose coverage of companies or sites that engage in chemical processing, but that are classified under some other primary SIC code. This is why the proposed amendment placed its emphasis on end products of a site.

After careful review the Agency has determined that the GE proposal provides a way to accomplish the goals of this proposed amendment and remove from this part of the regulation the specific dependence on SIC code listings. The Agency agrees that the types of "sole" processors the agency intends to cover are those who produce and market chemical mixtures (including solutions) and those firms that repackage chemical substances or mixtures. This recommendation actually enhances the regulatory language because it expresses the Agency's intent to cover repackagers as processors. Such coverage is referenced only indirectly in the current language.

C. Issues Not Related to Proposed Amendments

1. Dow raised a question concerning a company's recordkeeping responsibility if it is one of two owners of an evenly owned subsidiary. Dow contends that in such cases the parent companies should not be responsible for section 8(c) recordkeeping. EPA's opinion is that the most reasonable course in such a case is to have the evenly owned subsidiary assume primary responsibility for recordkeeping and reporting when required under section 8(c). The two parent companies and the subsidiary should, of course, be in agreement on this course of action and, if necessary, either parent should be able to direct EPA to such records.

2. GE states that EPA has nowhere adequately discussed the relationship between section 8(c) and (e) of TSCA. They ask that EPA address this issue in the **Federal Register.**

Part of the public record of the proposed amendments are two question and answer documents prepared by EPA on the section 8(c) rule and distributed to the public. Both documents answer several questions about the section 8(c)/8(e) relationship. Excerpted and reproduced below are representative questions and answers:

Question. What is the relationship of section 8(c) records to section 8(e) reporting? Does the 15-day deadline for 8(e) reporting apply to the receipt of section 8(c) allegations?

Answer. EPA believes that section 8(c) records will be one of several sources of information that can provide "reasonable support for the conclusion that a substance poses a substantial risk to health or the environment." The 15-day "clock" for section 8(e) reporting starts at the point where a company official or employee capable of appreciating the significance of the information determines that such information provides that "reasonable support . . ." It is conceivable that just one recordable significant adverse reaction could be the trigger. Much depends on the content of the allegation. It is, perhaps, more reasonable to expect that a pattern of effects recognized from the accumulation of several allegations will, in combination with other data obtained,

lead to the determination that a section 8(e) notice must be submitted.

Question: What distinguishes 8(e) from 8(c)? What are the similarities and differences?

Answer. The 8(c) rule is primarily a recordkeeping rule, while 8(e) is a reporting requirement. The 8(c) rule requires that allegations of significant adverse reactions to health or the environment be kept whereas section 8(e) requires that evidence of substantial risk of injury to health or the environment be reported to EPA. The source of the data handled under these two provisions is also different; allegations are likely to be received from workers, consumers, and plant neighbors, while 8(e) submissions usually result from designed, controlled studies and reports strongly implicating a chemical. Section 8(e) health effects submissions focus on new serious health effects. Section 8(e) submissions are also triggered by information about significant changes in exposure circumstances with a recognized hazardous substance. Section 8(c) allegations may focus on serious health effects, but can also report lesser effect experienced by a group of individuals, or repeatedly by an individual. Both rules contain exemptions: 8(c) exempts known human effects in the scientific literature, material safety data sheets, or labeling. 8(e) exempts effects reported to EPA under other statutes, and known effects in the scientific literature.

III. Final Amendments

Based on a consideration of comments received, the Agency has determined that it will adopt the amendments to the TSCA section 8(c) rule as discussed below.

A. Exemption of Coincidental Manufacturers

The amendment regarding exemption of coincidental manufacturers is added to paragraph (2) of § 717.7(a) of the regulation. This language is adopted from similar provisions in the TSCA Inventory and PMN regulations. The difference is that this provision applies to persons whose only manufacturing act is to produce a substance coincidentally. It does not in any way exempt from the rule such substances or allegations about such substances. The amendment includes paragraphs added to § 717.5 in order to insure that allegations regarding coincidentally produced substances are considered for recordkeeping by those manufacturers and processors that are subject to the rule. Specifically, these are § 717.5(a)(2)(iv) and (b)(2)(iv).

B. Revision of Processors Subject to the Rule

Amendment language that revises the description of processors subject to the rule can be found under § 717.5(b)(1). As discussed above, this amendment changes the emphasis of the processor designation from a dependence on certain SIC code designations to whether a company is producing mixtures or is involved in repacking chemical substances or mixtures. Section 717.5(b)(2) discusses the types of allegations that processors must collect. Language in § 717.5(b)(2)(i) has been modified to be consistent with removal of references to the SIC codes.

Section 717.7(b) has been deleted from the rule. The Agency has determined that this paragraph is unnecessary because, as an exemption, it functioned only to state the converse of § 717.5(b)(1).

IV. Public Record

EPA has established a public record for this rulemaking [Docket number OPTS–83001D]. The record, along with a complete index, is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in the OTS Reading Room, Rm. E–107, 401 M St., SW., Washington, D.C. 20460. This record includes basic information that the Agency considered in developing the proposed amendments and comments received on the proposal. The record includes the following documents.

1. The final rule implementing TSCA section 8(c).
2. The proposed amendments.
3. Letters from the law office of Wald, Harkrader and Ross representing the American Paper Institute (September 27, 1983, November 22, 1983, December 16, 1983 and December 20, 1983).
4. Documents regarding questions and answers on the final section 8(c) rule dated November 1983 and July 1984.
5. Comments from the following organizations: Chemical Manufacturers Association, Chemical Specialties Manufacturers Association, Environmental Defense Fund, General Electric Company, National Paints and Coatings Association and the Dow Chemical Company.
6. This final rulemaking.

V. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. The final regulation implementing TSCA section 8(c) is not major because it does not have an effect of $100 million or more on the economy. The Agency has further determined that the final amendments in this notice will not change the status of the regulation for the purposes of E.O. 12291 review.

This regulation has been submitted to the Office of Management and Budget for review as required by E.O. 12291.

B. Regulatory Flexibility Act

These amendments are consistent with the objectives of the Regulatory Flexibility Act (Pub. L. 96–354) because under the Agency's criteria, they will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., authorizes the Director of the Office of Management and Budget to review certain information collection requests by Federal agencies. The reporting provisions of the final TSCA section 8(c) rule were approved in October of 1983 and confirmed in the **Federal Register** of June 5, 1984 (49 FR 23182) and carry the OMB control No. 2070–0017.

The amendments in this notice do not change the recordkeeping or reporting provisions of the rule. They are designed to clarify which chemical manufacturers and processors are subject to the rule. This will not result in an increase in the number of persons subject to the rule and may actually result in a decrease in the impact of the rule on the regulated community through clarifying the rule's requirements.

List of Subjects in 40 CFR Part 717

Environmental protection, Hazardous substances, Chemicals, Recordkeeping and reporting requirements, Significant adverse reactions.

Dated: November 1, 1985.

Lee M. Thomas,

Administrator.

PART 717—[AMENDED]

Therefore, 40 CFR Chapter I, Part 717 is amended as follows:

1. The authority citation for Part 717, Subpart A is revised to read as follows:

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

2. In § 717.5, paragraph (a)(2)(iv) is added, paragraphs (b)(1) and (2)(i) are revised; and paragraph (b)(2)(iv) is added to read as follows:

§ 717.5 Persons subject to this Part.

(a) * * *

(2) * * *

(iv) Any allegation identifying a substance produced coincidentally during processing, use, storage or disposal of a chemical substance it manufactures.

* * * * *

(b) *Processors.* (1) A person who processes chemical substances, who is not also a manufacturer of those chemical substances, is subject to this Part if (i) the person processes chemical substances to produce mixtures, or (ii) the person repackages chemical substances or mixtures.

* * * * *

(2) * * *

(i) Any allegation identifying any mixture it produces and distributes in commerce and any allegation identifying any chemical substance or mixture it repackages and distributes in commerce.

* * * * *

(iv) Any allegation identifying a substance produced coincidentally during the processing, use, storage or disposal of the products described in paragraph (b)(2)(i) of this section.

* * * * *

3. In § 717.7, the text following the title "Manufacturers" is redesignated as paragraph (a)(1), paragraph (a)(2) is added, and paragraph (b) is removed and reserved as follows:

§ 717.7 Persons not subject to this part.

(a) *Manufacturers.*

(1) * * *

(2) A person is not subject to this Part if the chemical substances that person causes to be produced are limited to:

(i) Chemical substances that result from chemical reactions that occur incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(ii) Chemical substances that result from chemical reactions that occur incidental to storage or disposal of other chemical substances, mixtures, or articles.

(iii) Chemical substances that result from chemical reactions that occur upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleaners or other housekeeping products, fuel additives, water softening and treatment agents, photographic films, batteries, matches, or safety flares, and that are not themselves manufactured or imported for distribution in commerce for use as chemical intermediates.

(iv) Chemical substances that result from chemical reactions that occur upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance.

(v) Chemical substances that result from chemical reactions that occur when (A) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation-inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH adjuster, sequestrant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (B) a chemical substance, which is intended solely to impart a specific physicochemical characteristic, functions as intended.

(b) [Reserved]

* * * * *

[FR Doc. 85-26939 Filed 11-12-85; 8:45 am]
BILLING CODE 6560-50-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 2780

[Circular No. 2572]

Special Areas; Final Rulemaking Removing Provisions Relating to Lands Within the Choctaw-Chickasaw Nations and Arkansas Drainage Districts

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rulemaking.

SUMMARY: This final rulemaking removes from Title 43 of the Code of Federal Regulations the existing regulations covering lands within the Choctaw-Chickasaw Nations and Arkansas Drainage Districts. These regulations are no longer needed because the Act of August 3, 1955, and the Act of January 17, 1920, were repealed by the Federal Land Policy and Management Act of 1976. The regulations have been retained to facilitate the handling of any actions pending at the time of repeal.

EFFECTIVE DATE: December 13, 1985.

ADDRESS: Any suggestions or inquiries should be sent to: Director (320), Bureau of Land Management, Main Interior Bldg. Room 3643, 1800 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Gary L. Rowe, (202) 343-8693.

SUPPLEMENTARY INFORMATION: This final rulemaking removes from the existing regulations provisions covering lands within the Choctaw-Chickasaw Nations and Arkansas Drainage Districts, 43 CFR Subparts 2781 and 2784, respectively. These provisions are being removed because they were repealed by the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.). Specifically, the Act of August 3, 1955 (43 U.S.C. 1102), authorizing the Secretary of the Interior to manage and dispose of any interest in lands which were conveyed to the United States by the Choctaw-Chickasaw Nations, and the Act of January 17, 1920 (43 U.S.C. 1041-1048), providing that all unreserved public lands within certain townships in Arkansas were subject to the laws of the State of Arkansas relating to organization of water drainage districts, were repealed. The regulations have been retained to facilitate the handling of any actions that might have been pending at the time the two Acts were repealed. All pending actions have been completed and the regulations are no longer needed. This administrative action removes these regulations from the Code of Federal Regulations. Even though all actions covered by the two Acts have been completed, rights, such as life estates and sales, granted pursuant to the Acts, may still exist. The Bureau of Land Management does not expect any issues to arise under these existing rights requiring consideration under the regulations that are being removed by this final rulemaking. However, should any questions arise concerning rights previously granted under these regulations, earlier editions of the Code of Federal Regulations will remain available to assist in interpretation.

The principal author of this final rulemaking is Gary L. Rowe, Division of Lands, Bureau of Land Management, assisted by the staff of the Office of Legislation and Regulatory Management, Bureau of Land Management.

It is hereby determined that this rulemaking does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1968 (42 U.S.C. 4332(2)(C)) is required.

The Department of the Interior has determined that this document is not a major rule under Executive Order 12291 and that it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

There are no information collection requirements contained in this final rulemaking requiring the approval of the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 43 CFR Part 2780

Irrigation, Public lands—sales, Reclamation.

Under the authority of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.), Part 2780, Group 2700, Subchapter B, Chapter II of Title 43 of the Code of Federal Regulations is amended as set forth below.

Dated: November 4, 1985.

J. Steven Griles,

Deputy Assistant Secretary of the Interior.

PART 2780—[AMENDED]

1. The authority citation for Part 2780 is revised to read:

Authority: R.S. 2478; 43 U.S.C. 1201, unless otherwise noted.

2. Part 2780 is amended by:

§§ 2781.0–3—2781.6 (Subpart 2781) and §§ 2784.0–3—2784.9 (Subpart 2784) [Removed]

a. Removing Subparts 2781 and 2784 in their entirety; and

§§ 2783.0–3—2783.9 (Subpart 2783) [redesignated as § 2781.0–3—2781.9 (Subpart 2781)]

b. Redesignating Subpart 2783, §§ 2783.0–3 through 2783.9, as Subpart 2781, §§ 2781.0–3 through 2781.9.

[FR Doc. 85–26949 Filed 11–12–85; 8:45 am]
BILLING CODE 4310–84–M

Proposed Rules

Federal Register
Vol. 50, No. 219
Wednesday, November 13, 1985

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

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 426

[Amdt. 2; Doc. No. 0028A]

Combined Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to amend the Combined Crop Insurance Regulations (7 CFR Part 426), effective for the 1986 and succeeding crop years by revising and reissuing section 426.7. The intended effect of this rule is to: (1) change to a mandatory "Actual Production History" (APH) basis by removing the Premium Adjustment Table and providing for cancellation for not furnishing records; and (2) change the method of computing indemnities when acreage, share, or practice is underreported. The authority for the promulgation of this rule is contained in the Federal Crop Insurance Act, as amended.

DATES: Written comments, data, and opinions of this proposed rule must be submitted not later than December 13, 1985, to be sure of consideration.

ADDRESS: Written comments on this proposed rule should be sent to the Office of the Manager, Federal Crop Insurance Corporation, Room 4096, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, D.C., 20250, telephone (202) 447-3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation No. 1512-1. This action constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is October 25, 1990.

Merritt W. Sprague, Manager, FCIC, has determined and certifies that this action (1) is not a major rule as defined by Executive Order No. 12291 because it will not result in: (a) an annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) will not increase the federal paperwork burden for individuals, small businesses, and other persons.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Other than minor changes in language and format, the principal changes in the combined crop policy are:

1. Section 3.b.—When acres are underreported, the production from all acres will be applied against the reported acres in calculating indemnities. This change will reduce the indemnities when acres are underreported and will reduce the complexity of calculations.

2. Section 4.—Remove the Premium Adjustment Table. The crop will be insured on an actual production history (APH) basis. Coverages will, therefore, reflect the actual production history of the crop on the unit. Insureds with good loss experience who are now receiving a premium discount are protected since they may retain a discount under the present schedule through the 1990 crop year or until their loss experience causes them to lose the advantage, whichever is earlier.

3. Section 6.—Add a new section to cancel the contract if production history is not furnished by the cancellation date. An exception will be allowed if the insured can show, prior to the cancellation date, that records are unavailable due to conditions beyond the insured's control. This clause is required by the proposed change to mandatory APH.

FCIC is soliciting public comment on this proposed rule for 30 days after publication in the **Federal Register**. Written comments will be available for public inspection in the Office of the Manager, Room 4096, South Building, U.S. Department of Agriculture, Washington, D.C., 20250, during regular business hours, Monday through Friday.

List of Subjects in 7 CFR Part 426

Crop insurance, Combined crop.

Proposed rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation hereby proposes to amend the Combined Crop Insurance Regulations (7 CFR Part 426), effective for the 1986 and succeeding crop years, as follows:

PART 426—[AMENDED]

1. The authority citation for 7 CFR Part 426 continues to read as follows:

Authority: Secs. 506, 516, Pub. L. 75-430, 52 Stat. 73, 77, as amended (7 U.S.C. 1506, 1516).

2. 7 CFR 426.7 is revised to read as follows:

§ 426.7 The policy.

(a) In accordance with the provisions governing changes in the contract contained in policies issued under FCIC regulations for the 1986 and succeeding crop years, a contract in the form provided for in this subpart will come into effect as a continuation of a combined crop insurance contract issued under such prior regulations, without the filing of a new application.

(b) The provisions of the Combined Crop Insurance Policy for the 1986 and succeeding crop years are as follows:

DEPARTMENT OF ARICULTURE

Federal Crop Insurance Corporation

Combined Crop; Crop Insurance Policy

(This is a continuous contract. See the provisions of the individual crop policies)

AGREEMENT TO INSURE: We will provide the insurance described in this policy in return for the premium and your compliance with all applicable provisions.

Throughout this policy, "you" and "your" refer to the insured shown on the accepted Application and "we," "us, " and "our" refer to the Federal Crop Insurance Corporation.

Terms and Conditions

1. Applicability.

The provisions for each insured crop contained in the individual policy for such crop will apply except as otherwise provided herein. For the purpose of combined crop insurance, those parts of the individual policies which refer to individual crops will be considered to mean all crops insured under this policy.

2. Crop acreage and share insured.

In addition to section 2 of the applicable individual crop policies, the following will apply:

a. The crops insured are all of the crops grown on insured acreage and for which production guarantees and premium rates are provided by the actuarial table for combined crop insurance.

b. Insurance will not be considered to have attached to any acreage of rye for any crop year when the contract is canceled or terminated for indebtedness for that crop year.

3. Annual Premium.

In lieu of section 5 of the applicable individual crop policies, the following will apply:

a. The annual premium is earned and payable at the time of planting. The amount is computed by multiplying the applicable diversification factor(s) times the applicable premium factor(s).

b. Interest will accrue at the rate of one and one-half percent (1½%) simple interest per calendar month, or any part thereof, on any unpaid premium balance starting on the first day of the month following the first premium billing date.

c. If you are eligible for a premium reduction in excess of 5 percent based on your insuring experience through the 1984 crop year under the terms of the experience table contained in the combined crop policy in effect for the 1985 crop year, you will continue to receive the benefit of that reduction subject to the following conditions:

(1) No premium reduction will be retained after the 1990 crop year;

(2) The premium reduction will not increase because of favorable experience;

(3) The premium reduction will decrease because of unfavorable experience in accordance with the terms of the policy in effect for the 1985 crop year;

(4) Once the loss ration exceeds .80, no further premium reduction will apply; and

(5) Participation must be continuous.

4. Claim for indemnity.

In lieu of subsection 9(c) of the applicable individual crop policies, the following will apply:

a. The indemnity will be determined on each unit by:

(1) Multiplying the insured acreage for each insured crop on the unit times the applicable production guarantee, times the applicable price election, times your share;

(2) Multiplying the total production to be counted for each insured crop on the unit, times the applicable price election, times your share;

(3) Adding the dollar amounts obtained for each of the respective insured crops in (1) above; and

(4) Adding the dollar amounts obtained for each of the respective insured crops in (2) above, and subtracting this sum from the sum obtained in (3) above.

b. If the information reported by your results in a lower premium than the actual premium determined to be due, the dollar amounts in (3) above will be computed on the information reported, but all production from insurable acreage, whether or not reported as insurable, will be counted in (2) above.

5. Yield records.

In lieu of section 15.c. of the individual crop policies and prior to the cancellation date for any crop year you must:

(1) Furnish to the Corporation, satisfactory production records for the previous crop year or the contract will be cancelled for the subsequent crop year; or

(2) Show to our satisfaction that the records are not available because of conditions beyond your control, such as fire, flood or other natural disaster, (If this section (2) applies, the Field Actuarial Office may assign a yield for the year for which the records are unavailable).

You may furnish the records required by this section for any crop year prior to that crop year's cancellation date. Your election of this option will result in the inclusion of that crop year's production information in the next year's yield guarantee.

6. Cancellation and termination dates.

In lieu of section 15.e. of the applicable individual crop policies, the cancellation and termination dates are April 15.

7. Contract changes.

In lieu of section 16 of the applicable crop policies, we may change any terms and provisions of the contract from year to year. If your price election at which indemnities are computed is no longer offered, the actuarial table will provide the price election which you are deemed to have elected. All contract changes will be available at your service office by December 31 preceding the cancellation date. Acceptance of any change will be conclusively presumed in the absence of notice from you to cancel the contract.

8. Meaning of terms.

For the purposes of combined crop insurance:

a. "Actuarial table," in lieu of the definition of actuarial table in section 17 of the applicable crop policies, means the forms and related material for the crop year approved by us which are on file for public inspection in the service office, and which show the production guarantees, coverage levels, premium factors, dollar coverage per acre, applicable prices for computing indemnities, the applicable diversification factor table, insurable and uninsurable acreage, and related information regarding combined crop insurance in the county.

b. "Diversification factor" means a factor applied to reduce the premium when there is a diversity of crops planted. The factor is provided by the county actuarial table.

c. "Premium factor" means the factor provided in the county actuarial table for use in determining the premium.

d. "Unit," in lieu of the unit definition in section 17 of the applicable crop policy, means all of the insurable acreage of all applicable insured crops in the country at the time of planting for the crop year:

(1) In which you have a 100 percent share; or

(2) Which is owned by one entity and operated by another entity on a share basis.

Land rented for cash, a fixed commodity payment, or any consideration other than a share in the crop(s) on such land will be considered as owned by the lessee. Land which would otherwise be one unit may be divided according to applicable guidelines on file in your service office. Units will be determined when the acreage is reported. Errors in reporting units may be corrected by us to conform to applicable guidelines when adjusting a loss. We may consider any acreage and share thereof reported by or for your spouse or child or any member of your household to be your bona fide share or the bona fide share of any other person having an interest therein.

Done in Washington, D.C., on October 25, 1985.

Edward Hews,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 85-26976 Filed 11-12-85; 8:45 am]

BILLING CODE 3410-08-M

Agricultural Marketing Service

7 CFR Part 928

[Docket No. AO-371-A1]

Papayas Grown in Hawaii

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Public hearing on proposed rulemaking.

SUMMARY: Notice is hereby given of a public hearing to be held to consider proposed amendment of the marketing agreement and Marketing Order 928 (7 CFR Part 928) covering papayas grown in Hawaii.

The proposed amendments would provide for a public member on the committee and authorize changes in the number of grower or handler members on the committee, limit committee member tenure to 3 consecutive 2-year

terms of office, allow the committee members to nominate persons to fill vacancies on the committee under certain circumstances, require an affirmative vote by a majority of the committee members to recommend an action, provide authority for a late payment charge on past due assessments, add authority for marking packages of papayas and provide for lot identification at the time of inspection, permit different grade, size, container or pack regulations for papayas shipped to different marketing zones, e.g. specific countries or groups of countries, and provide for periodic continuance referenda.

DATE: The hearing will begin at 10:00 a.m., Wednesday, November 20, 1985.

ADDRESS: The hearing will be held in the Kilohana Room in the Naniloa Surf Hotel, Banyan Drive, Hilo, Hawaii.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, Telephone: 202–447–5975. Copies of this notice of hearing and the marketing order are available from Mr. Doyle.

SUPPLEMENTARY INFORMATION: The amendments were proposed and the hearing requested by the Papaya Administrative Committee established under the marketing agreement and order regulating the handling of papayas grown in Hawaii. The Department of Agriculture proposes that it be authorized to make any necessary conforming changes which may result from this hearing.

This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and therefore is excluded from the requirements of Executive Order 12291.

The Regulatory Flexibility Act (Pub. L. 96–345), effective January 1, 1981, seeks to ensure that, within the statutory authority of a program, the regulatory and information requirements are tailored to the size and nature of small businesses. Interested persons are invited to present evidence at the hearing on the probable regulatory and informational impact of the proposals on small business.

The hearing is called pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR Part 900). The proposed amendments of the marketing agreement and order have not received the approval of the Secretary of Agriculture.

The public hearing is for the purpose of: (1) Receiving evidence about the economic and marketing conditions which relate to the proposed amendments of the marketing agreement and order; (ii) determining whether there is a need for the proposed amendments to the marketing agreement and order; and (iii) determining whether the proposed amendments or appropriate modifications of them will tend to effectuate the declared policy of the act.

List of Subjects in 7 CFR Part 928

Marketing agreements and orders, Papayas, Hawaii.

PART 928—PAPAYAS GROWN IN HAWAII

The authority citation for 7 CFR Part 928 continues to read:

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

Proposals of the Papaya Administrative Committee are as follows:

Proposal No. 1

Amend § 928.20 to read as follows:

§ 928.20 Establishment and membership.

There is hereby established a Papaya Administrative Committee consisting of thirteen members, each of whom shall have an alternate who shall have the same qualifications as the member. Ten of the members and their alternates shall be growers and are referred to as "grower" members of the committee. Seven of the ten grower members and their alternates shall be producers of papayas in District 1, two grower members and their alternate shall be producers of papayas in District 2, and one grower member and alternates shall be producers of papayas in District 3. No grower organization shall be permitted to have more than three members on the committee. The three handler members and their alternates shall be selected from the production area at large. No handler organization shall be permitted to have more than one handler member on the committee. The number of grower and handler members and alternates on the committee may be change as provided in § 928.31(o). The committee may be increased by one public member and one alternate nominated by the committee and selected by the Secretary. The committee, with the approval of the Secretary, shall prescribe qualifications, term of office and procedure for nominating the public member and alternate.

Proposal No. 2

Amend § 928.21 by adding a sentence at the end of the paragraph to read as follows:

§ 928.21 Term of office.

* * * The consecutive terms of office of a member shall be limited to three 2-year terms.

Proposal No. 3

Amend § 928.22 by adding a new paragraph (c) to read as follows:

§ 928.22 Nomination.

* * * * *

(c) In the event that nominees for all available positions are not provided by the aforesaid procedure, then such unfilled positions shall be treated as vacancies and the provisions of § 928.26 shall apply.

Proposal No. 4

Amend § 928.26 by adding a proviso and a sentence at the end of the first sentence to read as follows:

§ 928.26 Vacancies.

* * *: *Provided,* That the committee may submit its recommendation to the Secretary of a nominee eligible to serve in accordance with the requirements specified in § 928.20. To the extent practicable, the committee's recommended nominee for a producer member or alternate member position to represent a particular district shall be a nominee nominated to the committee by the incumbent producer representatives of the committee from that district and the recommended nominee for a handler member or alternate handler member position shall be the nominee nominated to the committee by the incumbent handler representatives of the committee. * * *

Proposal No. 5

Amend § 928.31 by revising paragraph (o) to read as follows:

§ 928.31 Duties.

* * * * *

(o) With the approval of the Secretary to redefine the districts into which the production area is divided, to reapportion the grower representation of any district on the committee, or to increase or decrease the number of grower or handler members on the committee: *Provided,* That any such changes shall reflect, insofar as practicable, shifts in papaya production within the districts and the production area.

Proposal No. 6

Amend § 928.32 by revising paragraph (a) to read as follows:

§ 928.32 Procedure.

(a) A majority of all members of the committee shall be necessary to constitute a quorum and such majority must concur to approve any committee action.

* * * * *

Proposal No. 7

Amend § 928.41 by revising the last sentence in paragraph (b) to read as follows:

§ 928.41 Assessments.

* * * * *

(b) * * * Assessments not paid within a period of time prescribed by the committee may be made subject to interest or late payment charges, or both. The period of time, rate of interest, and late payment charge shall be as recommended by the committee and approved by the Secretary: *Provided,* That when interest or late payment charges are in effect, they shall be applied to all assessments not paid within the prescribed period of time.

Proposal No. 8

Amend § 928.52 by revising paragraph (a)(3) and paragraph (a)(4) to read as follows:

§ 928.52 Issuance of regulations.

(a) * * *

(3) Fix the size, capacity, weight, dimension, marking, or pack of the container, or containers, which may be used in the packaging or handling of papayas.

(4) Prescribe different requirements under subparagraphs (1) through (3) of this paragraph applicable to the handling of papayas to local (inter-island) and export destinations. Such requirements may be different for any variety and for the handling of such fruit to any island, county, country, groups of countries, or larger geographical area. For this purpose, the committee, with the approval of the Secretary, may establish marketing zones.

* * * * *

Proposal No. 9

Amend § 928.55 by adding a new paragraph (c) to read as follows:

§ 928.55 Inspection and certification.

* * * * *

(c) The committee may, with the approval of the Secretary, prescribe such rules and regulations as it may deem necessary to assure compliance with this section and provide for identification of packages of papayas which have been inspected and certified for handling.

Proposal No. 10

Amend § 928.64 by redesignating paragraph (e) as paragraph (f) and adding a new paragraph (e) to read as follows:

§ 928.64 Termination.

* * * * *

(e) The Secretary shall conduct a referendum by October 1 of the tenth year following the effective date of this section and no later than October 1 every tenth year thereafter to find whether, in accordance with paragraph (c) of this section, continuance of the order is favored by producers: *Provided,* That in the event a referendum for a substantive amendment of the order is conducted within the 10-year period, and the amendment is approved by producers, no continuance referendum will be held during the 10-year period: *Provided further,* That prior to conducting a continuance referendum, the committee shall conduct an informal mail survey among all growers to determine if there is a need for a continuance referendum. The ballots of the informal mail survey shall be mailed to and tabulated by the Secretary or a representative appointed by the Secretary.

* * * * *

Proposal of the Fruit and Vegetable Division, Agricultural Marketing Service, Department of Agriculture:

To make such changes as may be necessary to make the marketing agreement and order conform with any amendments thereto that may result from the hearing.

Dated: November 8, 1985.

William T. Manley,

Deputy Administrator, Marketing Programs.

[FR Doc. 85-27102 Filed 11-12-85; 8:45 am]

BILLING CODE 3410-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 85-NM-23-AD]

Airworthiness Directives: HTL Advanced Technology Fire Extinguisher Discharge Outlets Installed on Boeing Models 707, 727, 737, 747, 757, and 767 Series Airplanes, and on Airbus Industrie Models A300 and A310 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Amendment to Notice of Proposed Rulemaking (NPRM); Reopening of Comment Period.

SUMMARY: This document amends an earlier proposed airworthiness directive (AD) that would require physical and x-ray inspections of certain HTL Advanced Technology fire extinguisher discharge outlets. Since the proposal was published, the FAA has determined that the proposed AD should also be made applicable to Airbus Industrie Model A300 series airplanes; that additional HTL Advanced Technology service bulletins should be referenced in the proposed AD; and that the proposal should reference only later versions of certain service bulletins referenced in the original proposal. It is necessary to amend the original proposal to accomplish these changes.

DATES: Comments must be received no later than January 3, 1986.

ADDRESSES: Send comments on the proposal in duplicate to Federal Aviation Administration, Northwest Mountain Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 86-NM-23-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from HTL Advanced Technology, 1800 Highland Avenue, Duarte, California 91010, Attention: J.W. Battis, Vice-President-Quality Assurance. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at 4344 Donald Douglas Drive, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Roy A. McKinnon, Aerospace Engineer, Propulsion Branch, ANM-140L, FAA, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California 90808; telephone (213) 548-2835.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

contained in this Notice may be changed in light of the comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA/public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Availability of nprm

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the FAA, Northwest Mountain Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 85-NM-23-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

Discussion

A Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** on March 26, 1985 (50 FR 11892), which requested public comment concerning a proposal to require physical and x-ray inspections of certain HTL Advanced Technology fire extinguisher discharge outlets installed on certain Boeing and Airbus airplanes. Since the publication of the NPRM, the FAA has determined that the applicability of the proposed AD should be expanded to include the Airbus Industrie Model A300 series airplanes, and that several additional applicable HTL Advanced Technology Service Bulletins should be referenced in the proposal.

In addition, the x-ray inspection by the side view method, as described in the initial HTL Service Bulletins for the U.S. aircraft manufacturer, has been found to be unacceptable. Later versions of those service bulletins have eliminated references to that inspection method. Therefore, the proposed AD has been revised to include reference only to the later versions of the service bulletins.

Further, the FAA has determined that the proposed compliance time can be extended from twelve (12) months to eighteen (18) months without compromising safety. The proposed AD has been amended to reflect this.

It is estimated that approximately 5000 fire extinguisher discharge outlets installed on U.S. registered airplanes, or in inventory as spares, would be affected by this AD. It is estimated that 2 manhours per fire extinguisher discharge outlet are needed to accomplish the required inspections, at an average labor cost of $40 per manhour. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $400,000.

For these reasons, the FAA has determined that this document (1) involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979; and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact on a subtantial number of small entities because few, if any, airplance equipped with the applicable HTL Advanced Technology Fire Extinguishers are operated by small entities. A copy of a draft regulatory evaluation prepared for this action is contained in the regulatory docket.

PART 39—[AMENDED]

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend Section 39.13 of Part 39 of the Federal Aviation Regulation as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised), Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By amending Notice of Proposed Rulemaking, Docket 85-NM-23-AD, as published in the **Federal Register** on March 26, 1985 (50 FR 11892), as follows:

HTL Advanced Technology: Applies to HTL Advanced Techology fire extinguisher discharge outlets as listed in the service bulletins and installed on Boeing Models 707, 727, 737, 747, 757, and 767 series airplanes, and on Airbus Industrie Models A300 and A310 series airplanes.

To preclude the potential for separation of the fire extinguisher discharge outlet and misdirection of the fire extinguishing agent, accomplish the following within eighteen (18) months after the effective date of the AD, unless already accomplished.

A. Complete the physical and top view x-ray inspection specified in HTL Advanced Technology Service Bulletins (S/B) listed below, or later revisions approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region:

HTL Service Bulletins	Mfgrs. S/B
33600005-1-26-1—10-15-84 A300/A310	A300-26-048
35203600-26-A-3 Rev. C 6-15-85 747 ENG/APU.	747-26A2108
35203000-26-A-3 Rev. C 6-15-85 767 ENG/APU.	767-26A0019
35203010-26-A-1 Rev. A 6-15-85 707 ENG.	707-A341
35203016-26-A-2 Rev. B 6-15-85 737 ENG.	737-26A1029
35203018-26-A-2 Rev. B 6-15-85 727 ENG.	727-26A0034
35203021-26-A-2 Rev. B 6-15-85 737 APU.	737-26A1029
35203022-26-A-2 Rev. B 6-15-85 727 APU.	727-26A0034
35203030-26-A-1—8-31-84 A310 ENG	A310-26-2003
35203037-26-A-3 Rev. C 6-15-85 767 ENG/APU.	767-26A0019
35203036-26-A-1 Rev. A 6-15-85 767 Cargo.	767-26A0021
35203039-26-A-1 Rev. A 6-15-85 767 ENG/APU.	767-26A0019
35203040-26-A-1 Rev. A 6-15-85 767 ENG/APU.	767-26A0019
35289960-26-A-1 Rev. A 6-15-85 747 ENG/APU.	747-26A2110
35289950-26-A-1 Rev. A 6-15-85 757 Cargo.	757-26A0010
35289950-26-A-1 Rev. A 6-15-85 767 Cargo.	767-26A0021
35290250-26-A-2 Rev. B 6-15-85 747 APU.	747-26A2108

The inspections defined in the above Service Bulletins must be performed on all HTL fire extinguishers of the part numbers listed in the bulletins.

B. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

C. Alternate means of compliance which provide an acceptable level of safety may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

All persons affected by this proposal who have not already received these documents from the manufacturer may obtain copies upon request to the HTL Advanced Technology, 1800 Highland Avenue, Duarte, California 91010, Attention: J. W. Battis, Vice President-Quality Assurance. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at 4344 Donald Douglas Drive, Long Beach, California.

Issued in Seattle, Washington, on November 4, 1985.

Wayne J. Barlow,

Acting Director, Northwest Mountain Region.

[FR Doc. 85-26897 Filed 11-12-85; 8:45 am]

BILLING CODE 4910-13-M

---

14 CFR Part 39

[Docket No. 85-NM-120-AD]

Airworthiness Directives: Boeing Model 757-200 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice proposes to adopt an airworthiness directive (AD) that would require replacement of the existing elevator control forward override assembly cam on certain Boeing Model 757 airplanes. This action is prompted by a report of an incident during functional testing which resulted in jamming of both elevator control columns against the stops. This condition, if not corrected, could result in loss of elevator control.

DATES: Comments must be received on or before January 3, 1986.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 85–NM–120–AD, 17900 Pacific Highway South, C–68966, Seattle, Washington, 98168. The applicable service information may be obtained from the Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, FAA, Northwest Mountain Region, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Stanton Wood, Airframe Branch, ANM–120S; telephone (206) 431–2924. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C–68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

Comment Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, view, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rule Docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the FAA, Northwest Mountain Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 85–NM–120–AD, 17900 Pacific Highway South, C–68966, Seattle, Washington, 98168.

Discussion

During a recent functional testing of the elevator control system on a Boeing Model 757 airplane, it was found that the existing elevator forward override assembly cam provides inadequate length of contour, which may allow the cam roller to overrun the cam and become jammed if the captain's and first officer's control columns are forced in opposite directions against the stops. This situation requires approximately 190 pounds of force applied to each control column. The jamming of the control column results in loss of elevator control.

The Boeing Company issued Service Bulletin 757–27–0057 on July 26, 1985 (and Revision 1 on October 17, 1985), which provides instructions for removal and replacement of the elevator control forward override assembly cam.

Since this condition is likely to exist or develop on other airplanes of this same type design, an AD is proposed that would require operators to replace the existing elevator control forward override assembly cam with a revised cam, in accordance with the manufacturer's service bulletin.

It is estimated that 31 U.S. registered airplanes would be affected by this AD, that it would take approximately 4 manhours per airplane to accomplish the required modification, and that the average labor cost would be $40 per manhour. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $4,960.

For the reason discussed above, the FAA has determined that this document: (1) Involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have significant economic impact on a substantial number of small entities because few, it any, Boeing Model 757–200 airplanes are operated by small entities. A copy of a draft regulatory evaluation prepared for this action is contained in the regulation docket.

PART 39—[AMENDED]

List of Subjects 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

Boeing: Applies to all Model 757–200 series airplanes listed in Boeing Service Bulletin 757–27–0057, Revision 1, dated October 17, 1985, certification in any category.

To eliminate the possibility of the elevator forward override mechanism becoming jammed, accomplished:

A. Within the next 60 days after the effective date of this AD, remove and replace the elevator control forward override assembly cam with a revised cam in accordance with Boeing Service Bulletin 757–27–0057, Revision 1, dated October 17, 1985, of later FAA-approved revision.

B. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of the modifications required by this AD.

All persons affected by this proposal who have not already received these documents from the manufacturer may obtain copies upon request to the Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124–2207. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

Issued in Seattle, Washington, on November 4, 1985.

Wayne J. Barlow,

Acting Director, Northwest Mountain Region.

[FR Doc. 85–26898 Filed 11–12–85; 8:45 am]

BILLING CODE 4910–13–M

---

14 CFR Part 39

[Docket No. 85–NM–118–AD]

Airworthiness Directives; Gates Learjet Models 25, 25A, 25B, and 25C Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revise an existing airworthiness directive (AD) applicable to certain Gates Learjet Model 25 series airplanes, which would extend the inspection interval for Stall Warning Accelerometers from 165 hours to 220 hours time-in-service. this would permit operators to perform this inspection in conjunction with other airplane maintenance schedules.

DATE: Comments must be received on or before January 3, 1986.

ADDRESSES: Send comments on the proposal in duplicate to Federal Aviation Administration, Northwest Mountain Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 85–NM–118–AD, 17900 Pacific Highway South, C–68966, Seattle, Washington 98168. The applicable service information may be obtained from Gates Learjet Corporation, P.O. Box 7707, Wichita, Kansas 67277, or may be examined at FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Robert R. Jackson, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, Central Region, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4419.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA/public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to FAA, Northwest Mountain Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 85–NM–118–AD, 17900 Pacific Highway South, C–68966, Seattle, Washington 98168.

Discussion

Airworthiness Directive (AD) 82–01–04 R1, Amendment 39–4751, required an initial and repetitive inspection of the Stall Warning System on certain Gates Learjet Model 25 series airplanes. The repetitive inspection interval presently required is 165 hours time-in-service. Since the AD was adopted, Gates Learjet Corporation has revised its maintenance and inspection schedules. This proposed amendment would extend the maximum inspection interval as required by the existing AD from 165 hours time-in-service to 220 hours time-in-service; this interval would coincide with the Gates Learjet maintenance inspection schedule and the FAA Approved Aircraft Inspection Programs. The FAA has determined that this inspection interval can be extended without compromising safety.

In addition, this proposed amendment would also revise paragraph G. of the AD to reflect the correct address of the Wichita Aircraft Certification Office.

It is estimated that 180 airplanes of U.S. registry will be affected by this AD. It has been determined that the requirements of this proposed AD may actually reduce operators' costs since the required inspection may be accomplished in conjunction with other regularly scheduled airplane maintenance and inspections.

For these reasons, the FAA has determined that this document (1) involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 111034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities because few, if any, Gates Learjet Models 25, 25A, 25B, or 25C series airplanes are operated by small entities. A copy of a draft regulatory evaluation prepared for this action is contained in the regulatory docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

1. The authority citation for Part 39 continues to read:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

2. By revising paragraphs D. and G. of Airworthiness Directive (AD) 82–01–04 R1, Amendment 39–4751, as follows:

D. To assure proper operation of the Stall Warning Accelerometer Unit, unless previously inspected in the last 100 hours time-in-service before the effective date of this AD, witin the next 50 hours time-in-service, and at intervals not to exceed 220 hours time-in-service thereafter, perform the inspection of the Stall Warning Accelerometer in accordance with Gates Learjet Service Bulletin SB 23/24/25–301B, as appropriate.

G. Alternate means of compliance which provide an acceptable level of safety may be used when approved by the Manager, Wichita Aircraft Certification Office, FAA, Central Region, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209.

All persons affected by this proposal who have not already received the applicable service information from the manufacturer may obtain copies upon request to Gates Learjet Corporation, P.O. Box 7707, Wichita, Kansas 67277. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or FAA, Central Region, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas.

Issued in Seattle, Washington, on November 4, 1985.

Wayne J. Barlow,

Acting Director, Northwest Mountain Region.

[FR Doc. 85–26900 Filed 11–12–85; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 416

[Regulations No. 16]

Supplemental Security Income for the Aged, Blind, and Disabled; Resource Limits for Conditional SSI Payments

AGENCY: Social Security Administration, HHS.

ACTION: Proposed Rule.

SUMMARY: Current regulations for the Supplemental Security Income (SSI) program provide for conditional SSI payments to individuals who meet all eligibility criteria except that they have

nonliquid resources in excess of the statutory limits. The presumption is that since these individuals have little or no income or liquid resources with which to meet basic needs for food, clothing, or shelter, they need SSI while they dispose of their excess nonliquid resource(s). The current regulations provide special limits on the total and liquid resources an individual can own and receive conditional payments. The current regulations also require that any conditional payments made be repaid from the proceeds of the sale of the excess resource(s). The proposed regulation would eliminate the special limit on total resources but retain the special limit on liquid resources. The proposed regulation would also retain the requirement that any conditional payments made be repaid from the proceeds of the sale of the excess resource(s).

DATES: We are inviting public comments on this Notice of Proposed Rulemaking (NPRM). If we receive your comments no later than January 13, 1986, they will be considered in developing the final regulations.

ADDRESSES: Comments should be submitted in writing to the Acting Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, Maryland 21203, or delivered to the Office of Regulations, Social Security Administration, 3–A–3 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235, between 8:00 a.m. and 4:30 p.m. on regular business days. Comments received may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Henry D. Lerner, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone (301) 594–7463.

SUPPLEMENTARY INFORMATION: Section 1613(b) of the Social Security Act (the Act) grants the Secretary of Health and Human Services (the Secretary) the discretion to determine the period or periods of time within which, and the manner in which, various kinds of property must be disposed of in order to be included in determining an individual's eligibility for SSI payments. The Secretary also prescribes the requirements for the payment of benefits condition upon the disposal of such property.

The current regulations provide for conditional payments if total resources (liquid plus nonliquid) do not exceed $3,000 for an individual and $4,500 for a couple. Additionally, the liquid resources owned must not exceed one-fourth of the applicable dollar amount specified in section 1611(b)(1) of the Act in the case of an individual, and the amount specified in section 1611(b)(2) in the case of an individual and spouse, i.e., the annual Federal benefit rates. The current annual Federal benefit rate is $3,768 for an individual and $5,664 for a couple. Conditional SSI payments are made to an individual who is ineligible because he or she owns excess nonliquid resources to meet his or her basic needs for food, clothing and shelter while disposing of the excess nonliquid resources (real property within 6 months and other property within 3 months). Since recipients of conditional payments do not meet all the SSI eligibility requirements (i.e., they have excess resources) during the conditional payment period, the payments made are overpayments. Therefore, recipients must agree to repay these payments from the proceeds of the disposition. Similarly, recipients are also liable for repayment if the resource is not sold and no new current market value has been established. See below for discussion of the change in the "bona fide effort to sell" policy.

The proposed regulations will eliminate the limit on total resources but retain the limit on liquid resources. The effect will be to allow some additional individuals who have little or no income but who own nonliquid resources (e.g., an inherited house) that are difficult to sell, to receive conditional payments while they dispose of the resource. The increase in the number of individuals eligible for conditional payments as a result of this proposed change will be small, since current income requirements and the current limit on liquid resources will remain. In addition, most of these conditional payments should subsequently be recouped from these individuals from the proceeds of their resource dispositions.

The proposed regulations on conditional payments also revise the "bona fide effort to sell" policy to conform the policy for valuing resources in the conditional payments context to the general policy established for valuing resources reflected in Social Security Ruling SSR 83–30a. That policy is that resources must be valued at current market value (CMV) and when the CMV of an asset changes, the new CMV rather than the original CMV is used. (Note that property which cannot be sold at any price because of a legal bar to the transfer of ownership is not a resource for SSI purposes.)

The relationship of the two policies is as follows. When an individual requests conditional SSI payments of dispose of an excess resource, the individual signs an agreement to sell the excess resource and repay the conditional SSI payments with the proceeds. However, under existing conditional payments policy if an individual makes a "bona fide effort to sell" the resource and is unable to sell it at its estimated value, we currently treat the resource as if it had no value. Thus, the individual was not overpaid during the period he or she was attempting to dispose of the resource, and the individual is eligible for SSI payments. Although the "bona fide effort to sell" test is reevaluated at the time of redetermination, individuals may continue to receive SSI indefinitely.

Experience has demonstrated that often individuals cannot dispose of the excess resource(s) at the originally estimated value. It is possible, however, that the excess resource(s) could have been disposed of for cash at a lesser amount but well in excess of the SSI resource limit ($1,500 for an individual, $2,250 for a couple, effective January 1, 1985, $1,600/$2,400). Thus, the current policy allows individuals to retain valuable property in excess of the resource limits and still receive SSI for extended periods. Under the proposed rules, when time period for attempting to sell an excess resource expires (generally 6 months, or 9 months if good cause applies) and the resource has not been sold, the resource will be counted at market value. The market value originally estimated will be used unless the individual (at any time within the constraints of administrative finality) submits evidence (e.g., an estimate from a disinterested knowledgeable source) of a lesser current market value leading to a determination that he or she had no excess resources for the period and, thus, has not been overpaid. Individuals will be advised of this policy and the right to submit addtional evidence at the start and prior to the expiration of the conditional payment period. This policy recognizes that adverse market conditions may drive down the value of the excess resource (in extreme situations possibly to zero), without presuming that valuable property is valueless because the owner chooses not to sell at the price the market will bring.

Executive Order 12291: These proposed regulations have been reviewed under Executive Order 12291 and do not meet any of the criteria for a major regulation. Based on the best available information, both program and administrative costs would be negligible.

Paperwork Reduction Act: These proposed regulations impose no additional reporting or recordkeeping requirements requiring Office of Management and Budget clearance.

Regulatory Flexibility Act: We certify that these proposed regulations will not, if promulgated, have a significant economic impact on a substantial number of small entities because these rules affect only individuals and States. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96-354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 13.807, Supplemental Security Income program).

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income (SSI).

Dated: February 21, 1985.

Martha A. McSteen,

Acting Commissioner of Social Security.

Approved: May 21, 1985.

Margaret M. Heckler,

Secretary of Health and Human Services.

PART 416—[AMENDED]

Subpart L of Part 416 of Chapter III of Title 20 of the Code of Federal Regulations is amended as follows:

1. The authority citation for Subpart L of Part 416 continues to read as follows:

Authority: Secs. 1102, 1601, 1602, 1611, 1612, 1613, 1614(f), and 1631(d) of the Social Security Act, as amended; 49 Stat. 647, as amended, 86 Stat. 1465, 1466, 1468, 1470, 1473; 42 U.S.C. 1302, 1381, 1381a, 1382, 1382a, 1382b, 1382c(f), and 1383(d).

2. Section 416.1240 is amended by removing paragraph (a)(1), redesignating paragraphs (a)(2) and (3) as (a) (1) and (2), changing the reference in paragraph (b), and adding paragraph (c) to read as follows:

§ 416.1240 Disposition of resources.

(a) Where the resources of an individual (and spouse, if any) are determined to exceed the limitations prescribed in § 416.1205, such individual (and spouse, if any) shall not be eligible for payment except under the conditions provided in this section. Payment will be made to an individual (and spouse, if any) if:

(1) Total includable liquid resources (as defined in § 416.1201(b)) do not exceed one-fourth of the applicable dollar amount specified in section 1611(b)(1) of the Act in the case of an individual and in section 1611(b)(2) in the case of an individual and spouse; and

(2) The individual agrees in writing to:

(i) Dispose, at current market value, of the nonliquid resources (as defined in § 416.1201(c)) in excess of the limitations prescribed in § 416.1205 within the time period specified in § 416.1242; and

(ii) Repay any overpayments (as defined in § 416.1244) with the proceeds of such disposition.

(b) Payment made for the period during which the resources are being disposed of will be conditioned upon the disposition of those resources as prescribed in paragraph (a)(2) of this section. Any payments so made are (at the time of disposition) considered overpayments to the extent they would not have been paid had the disposition occurred at the beginning of the period for which such payments were made.

(c) If an individual fails to dispose of the resources prescribed in paragraph (a)(2) of this section, regardless of the efforts he or she makes to dispose of them, the resources will be counted at their current market value and the individual will be ineligible due to excess resources. The original estimate of current market value will be used unless the individual submits evidence establishing a lower value (e.g., an estimate from a disinterested knowledgeable source)

[FR Doc. 85-26942 Filed 11-12-85; 8:45 am]

BILLING CODE 4190-11-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD7-85-32]

Safety Zone; Tampa Bay, Hillsborough Bay and Approaches

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish local regulations governing the movement of vessels carrying anhydrous ammonia in heavily populated areas of Tampa Bay and Hillsborough Bay and their approaches and while the vessels are moored at receiving facilities. In view of the hazards associated with anhydrous ammonia, the Coast Guard deems it necessary to control the movement of anhydrous ammonia vessels and to establish marine safety zones surrounding these vessels in certain prescribed areas and under certain conditions.

DATE: Comments must be received on or before December 30, 1985.

ADDRESSES: Comments should be mailed to Commander (mps), Seventh Coast Guard District, 51 SW First Ave., Miami, FL, 33130. The comments will be available for inspection and copying at 51 SW First Avenue, Room 827, telephone (305) 350-5651. Normal office hours are between 7:30 a.m. and 4:00 p.m., Monday through Friday, except federal holidays. Comments may also be hand delivered to this address.

FOR FURTHER INFORMATION CONTACT: Lieutenant (j.g.) Harry D. Craig, Telephone (305) 350-5651.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this rulemaking by submitting written views, data, or arguments. Persons submitting comments should include their names and addresses, identify this notice (CGD7-85-32) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Receipt of comments will be acknowledged if a stamped self-addressed postcard or envelope is enclosed. All comments received before the expiration of the comment period will be considered before final action is taken on this proposal. The proposed rules may be changed in light of the comments received. No public hearing is planned, but one may be held if written requests for a hearing are received and it is determined that the opportunity to make oral presentations will aid the rulemaking process.

Drafting Information

The drafters of the notice are Lieutenant James H. McDowell, project officer, Coast Guard Marine Safety Office Tampa, and LCDR Kenneth E. Gray, project attorney, Seventh Coast Guard District Legal Office.

Discussion of Proposed Regulations

This action is being considered in view of the hazards associated with anhydrous ammonia. Anhydrous ammonia is generally carried aboard vessels as a liquid at a reduced temperature. In its natural state it is a colorless gas with a penetrating, pungent, and suffocating odor which is immediately dangerous to life and health at concentrations of 500 parts per million. The accidential release of a large amount of anhydrous ammonia such as that normally carried aboard a ship, in a populated area presents a serious threat to the well being of the community.

The Captain of the Port Tampa developed the proposed regulations after consulting with the primary users of Tampa Bay. The precaution of the floating safety zone is deemed necessary because the drafts of loaded

anhydrous ammonia vessels usually constrains them to the main ship channel. This limits their ability to take evasive action when operating within the confines of these channels or around the anhydrous ammonia receiving terminal. The chance of a collision is minimized by eliminating crossing, overtaking, or passing situations in the affected channels.

Loaded anhydrous ammonia vessels will be permitted to enter Tampa Bay and its approaches during daylight hours with a minimum of three miles visibility. The inherent risks of transporting anhydrous ammonia increases during periods of reduced visibility or at night. A cloud of anhydrous ammonia cannot be seen at night when visibility is reduced and would be difficult to track. Further, navigation at night is inherently more difficult. The safety zone is a "floating safety zone" and includes the entire width of the affected channels and 100 yards fore and aft of the anhydrous ammonia vessels. The parameters of the floating marine zone for loaded anhydrous ammonia carriers transiting Tampa Bay are as follows: Tampa Bay Cut "F" Channel Lighted Buoys "3F" and "4F" north through and including Gadsen Point Cut Lighted "3" and commencing at Garden Point Cut Lighted Buoys "7" and "8" north and including Hillsborough Cut "C" Channel to the southern tip of Hookers Point and into Port Sutton. For vessels bound for the anhydrous ammonia receiving facilities at Port Sutton. For vessels bound for the R. E. Knight anhydrous ammonia receiving facility at Hookers Point, the floating safety zone continues from Hillsborough Cut "C" Channel through Hillsborough Cut "D" Channel through Hillsborough Cut "D" Channel to the southern tip of Harbor Island. The floating safety zone is disestablished when the vessels are safely moored at the anhydrous ammonia receiving facilities at R. E. Knight Pier at Hookers Point or W. R. Grace or International Metals and Chemicals at Port Sutton.

A fixed safety zone is established which extends 150 feet waterside from an anhydrous ammonia vessel while it is moored at the receiving facilities at R. E. Knight on Hookers Point and W. R. Grace and International Metals and Chemicals at Port Sutton. Any vessels desiring to enter the fixed safety zone must obtain authorization from the Captain of the Port Tampa. Vessels transiting in the vicinity of the fixed safety zone should do so with as slow a speed as conditions permit. The fixed safety zone is deemed necessary to prevent surge to moored anhydrous ammonia vessels which may cause damage to moorings, transfer systems and/or loading arms and result in an anhydrous ammonia spill.

For anhydrous ammonia vessels departing port with cargo, the floating safety zone is establishing when they depart any of the above anhydrous ammonia receiving facilities and includes the same parameters as described above.

A passing window is provided for mariners between Gadsden Point Cut Lighted Buoy "3" and Gadsden Point Cut Lighted Buoys "7" and "8" where the floating safety zone is not in effect and vessel passing is permitted. The passing window is provided because deeper water outside the established channel permits vessels to give a wide berth to anhydrous ammonia vessels. This also facilitates the movement of traffic in upper Tampa Bay.

This proposed safety zone regulation would require persons to comply with the general safety regulations contained in 33 CFR 165.23 which prohibits persons from entering the safety zone without authorization from Captain of the Port. Mariners will be provided advance notice of scheduled anhydrous ammonia transits of Tampa Bay by broadcast Notice of Mariners.

The person directing the movement of the anhydrous ammonia vessel is not permitted to enter the safety zone if the time varies more than one half hour from the scheduled time stated in the broadcast Notice of Mariners. If the vessel's actual arrival at the safety zone will be more than one half hour from the scheduled time, permission must again be obtained from the Captain of the Port prior to commencing the transit. The Captain of the Port will take into consideration other vessel movements prior to rescheduling the safety zone.

Prior to commencing the movement, the person directing the movement of the anhydrous ammonia vessel shall make a security broadcast to advise other mariners of the intended transit. All additional security broadcasts, as recommended in the U.S. Coast Pilot, shall be made throughout the transit.

For incoming anhydrous ammonia carriers, a Coast Guard vessel will meet the anhydrous ammonia carrier at Tampa Cut "F" Channel Lighted Buoys "3F" and "4F" and escort it to the berth and will remain on scene to enforce the floating safety zone until the vessel is safely moored at the receiving facility. For outgoing vessels carrying anhydrous ammonia the process will be reversed.

Economic Assessment and Certification

These proposed regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. Anhydrous ammonia carriers have been transiting Tampa Bay for years. The conditions outlined herein for moving anhydrous ammonia vessels in Tampa Bay have been followed for at least five (5) years. In recent years, for each of these anhydrous ammonia vessel movements, the Captain of the Port Tampa has exercised his authority on a case by case basis and established a temporary floating safety zone in the form of Captain of the Port Orders. These Orders prescribed conditions for operating similar to those contained in this Notice of Proposed Rulemaking. By establishing a permanent rule the Coast Guard will enhance its ability to provide the public with the widest dissemination of the rule. Small and large companies are aware of the scheduled anhydrous ammonia transits and adjust their movements accordingly causing minimum economic impact.

The time constraint placed on the anhydrous ammonia vessel for its entrance to the safety zone is intended to allow non-regulated vessel operators to more efficiently schedule their movements and not be penalized by last minute changes by anhydrous ammonia vessels.

The fixed safety zone requires that vessels desiring to pass within 150 feet of a moored anhydrous ammonia vessel obtain permission from the Captain of the Port Tampa prior to doing so. This is not expected to be restrictive. Since the impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant impact on a substantial number of small entities.

List of Subjects in 33 CFR 165

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

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend Part 165 of Title 33, Code of Federal Regulations as follows:

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1225 and 1231; 50 U.S.C. 191; 49 CFR 1.46; and 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5

2. A new § 165.703 is added to read as follows:

§ 165.703 Tampa Bay, Flordia—safety zone.

(a) A floating safety zone is established consisting of an area 1000 yards fore and aft of a loaded anhydrous ammonia vessel and the width of the channel in the following areas:

(1) For inbound tank vessels loaded with anhydrous ammonia, Tampa Bay Cut "F" Channel from Lighted Buoys "3F" and "4F" north and including Tampa Bay Cut "D" Channel Lighted Buoy "3D" and commencing at Gadsden Point Cut Lighted Buoys "7" and "8" north and including Hillsborough Cut "C" Channel.

(i) For vessels bound for R. E. Knight Pier at Hookers Point the safety zone includes, in addition to the area in (a) (1), Hillsborough Cut "D" Channel to the southern tip of Harbor Island.

(ii) For vessels bound for the anhydrous ammonia receiving terminal at Port Sutton the safety zone includes, in additon to the area in (a) (1), Port Sutton Channel.

(2) For outbound tank vessels loaded with anhydrous ammonia the safety zone is established when the vessel departs the receiving terminal and continues through the area described in (a) (1).

(3) The floating safety zone is disestablished when the anhydrous ammonia carrier is safely moored at the anhydrous ammonia receiving facility.

(b) A safety zone is established which extends 150 feet waterside from an anhydrous ammonia vessel while it is moored at the receiving facilities at R. E. Knight on Hookers Point and W. R. Grace and International Metals and Chemicals at Port Sutton. Any vessels desiring to enter the safety zone must obtain authorization from the Captain of the Port Tampa. Vessels transiting in vicinity of the safety zone should do so with as slow a speed as conditions permit.

(c) The general regulations governing safety zones contained in 33 CFR 165.23 apply.

(d) The Marine Safety Office Tampa will notify the maritime community of periods during which these safety zones will in effect by providing advance notice of scheduled arrivals and departures of loaded anhydrous ammonia vessels via a marine broadcast Notice of Mariners.

(e) Should the actual time of entry of the anhydrous ammonia vessel into the safety zone vary more than one half hour from the scheduled time stated in the broadcast Notice to Mariners, the person directing the movement of the anhydrous ammonia vessel shall obtain permission from Captain of the Port Tampa before commencing the transit.

(f) Prior to commencing the movement, the person directing the movement of the anhydrous ammonia vessel shall make a security broadcast to advise mariners of the intended transit. All additional security broadcasts as recommended by the U.S. Coast Pilot 5, ATLANTIC COAST shall be made throughout the transit.

(g) Vessels carrying anhydrous ammonia are permitted to enter and transit Tampa Bay and Hillsborough Bay and approaches during daylight hours only with a minimum of three miles visibility.

(h) The Captain of the Port Tampa may waive any of the requirements of this subpart for any vessel upon finding that the vessel or class of vessel, operational conditions, or other circumstances are such that application of this subpart is unnecessary or impractical for purposes of port safety or environmental safety.

Dated: October 24, 1985.

R.P. Cueroni,

Rear Admiral, Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 85-26836, Filed 11-12-85; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-8-FRC-2922-4]

Approval and Promulgation of State Implementation Plans; Utah; Visibility

AGENCY: Environmental Protection Agency.

ACTION: Proposed Rulemaking.

SUMMARY: In this action, EPA proposes to approve the new source review (NSR) and monitoring plan for visibility in a revision to the Utah State Implementation Plan (SIP). This action is a result of rulemaking on October 23, 1984 (49 FR 42670), at which EPA proposed to disapprove SIPs of states which failed to comply with the provisions of 40 CFR 51.305 (visibility monitoring) and 51.307 (visibility NSR).

The Governor of Utah submitted a SIP Revision for Visibility Protection and the Visibility Regulation on April 26, 1985. Review of the plan and regulations indicates that Utah has met the criteria of 40 CFR 51.305 and 51.307.

DATE: Comments are due January 13, 1986.

ADDRESSES: Written comments should be addressed to: Robert R. DeSpain, Chief, Air Programs Branch, Environmental Protection Agency, One Denver Place, Suite 1300, 999 18th Street, Denver, Colorado 80202-2413.

Copies of the state submittal are available for public inspection between 8:00 a.m. and 4:00 p.m. Monday through Friday at the following location: Environmental Protection Agency, Region VIII, Air Programs Branch, One Denver Place, Suite 1300, 999 18th Street, Denver, Colorado 80202-2413.

FOR FURTHER INFORMATION CONTACT: Lee Hanley, Air Programs Branch, Environmental Protection Agency, One Denver Place, Suite 1300, 999 18th Street, Denver, Colorado 80202-2413, (303) 293-1757.

SUPPLEMENTARY INFORMATION:

Background

Section 169A of the Clean Air Act, 42 U.S.C. 7491, requires visibility protection for mandatory Class I Federal areas where EPA has determined that visibility is an important value. ("Mandatory Class I Federal areas" are certain national parks, wilderness areas, and international parks, as described in section 162(a) of the Act, 42 U.S.C. 7472(a), 40 CFR 11.400-937.) Section 169A specifically requires EPA to promulgate regulations requiring certain states to amend their State Implementation Plans (SIPs) to provide for visibility protection.

On December 2, 1980, EPA promulgated the required visibility regulations in 45 FR 80084, codified at 40 CFR 51.300 *et seq.* It required the states to submit their revised SIPs to satisfy those provisions by September 2, 1981. (See 45 FR 80091, codified in 40 CFR 51.302(a)(1).) That rulemaking resulted in numerous parties seeking judicial review of the visibility regulations. In March 1981, the Court stayed the litigation pending EPA action on related administrative petitions for reconsideration of the visibility regulations filed with the Agency.

In December 1982, the Environmental Defense Fund (EDF) filed suit in the U.S. District Court for the Northern District of California alleging that EPA failed to perform a nondiscretionary duty under section 110 of the Act to promulgate visibility SIPs. A negotiated settlement agreement between EPA and EDF required EPA to promulgate visibility SIPs on a specific schedule. It required EPA to propose to incorporate Federal regulations in States where SIPs are deficient with respect to the 1980 visibility new source review and monitoring regulations, 40 CFR 51.307 and 51.305, respectively. However, the

settlement allows a state an opportunity to avoid Federal promulgation if it submits a SIP by May 6, 1985. Utah is one of the states listed in 49 FR 42670 as having an inadequate New Source Review (NSR) and monitoring plan for visibility protection.

On April 26, 1985, the Governor of Utah submitted a SIP Revision for Visibility Protection and the Visibility Regulations for monitoring and new source review. The submittal cites the Utah Code Annotated 1953, as Amended, Section 26–13–1, as a policy of the State "to facilitate the enjoyment of natural attractions of the State." Utah has five mandatory Class I areas: Arches, Bryce Canyon, Canyonlands, Capitol Reef, and Zion National Parks. No other Class I areas currently exist in the State.

The SIP commits the State to visibility protection consistent with the Clean Air Act to be afforded within the park boundaries. The SIP is to be reviewed annually and revised as necessary.

Visibility Monitoring Strategy

40 CFR 51.305 requires all States with visibility protection areas to have a monitoring strategy for evaluating visibility in any mandatory Federal Class I area by visual observation or other appropriate monitoring techniques. The purposes of this requirement are to generate data for evaluating visibility impairment trends, determine potential impacts of new sources, assess the effectiveness of the visibility protection program, and identify major contributing sources. These purposes can be adequately addressed by determining the background visibility protection areas and documenting the extent of any visibility impairment that can be attributed by a source or small group of sources.

Visibility impairment is the human perception of the effects of natural or man-made conditions which reduce visual range or contrast, or coloration change. Thus, a visibility monitoring program should identify these effects as well as differentiate man-made effects from natural conditions. The program could generate various types of data such as reports from human observers, photographs, and/or automated instruments. The minimum data collection technique that 40 CFR 51.305 requires is visual observation. However, other more objective techniques are available. (See "Interim Guidance for Visibility Monitoring", Office of Air Quality Planning and Standards, November 1980 (EPA 450/2–80–082).

The monitoring section of the Utah Visibility Protection Plan consist of three components:

(1) Monitoring by the Federal Land Manager (FLM),

(2) Monitoring by sources proposing to locate or modify in an area where emissions may impact Class I areas, and

(3) Implementation of a state monitoring network.

"Monitoring by the FLM" is the assessment of visibility background and trends by obtaining existing data available from the FLM. The National Parks in Utah have been or are still being monitored by the National Park Service (NPS). For those areas where monitoring no longer occurs, the NPS feels there is sufficient background data, i.e., five to six years of monitoring data. For those areas where monitoring is still being conducted, the State is seeking a cooperative agreement with the NPS to facilitate visibility monitoring and data exchange. Currently, the NPS performs visibility monitoring at the following sites:

(1) Bryce Canyon National Park,
(2) Zion National Park,
(3) Capitol Reef National Park, and
(4) Canyonlands National Park.

Monitoring by sources proposing to locate or modify in the locale where emissions may impact Class I areas will add to the background and trend data bank of that Class I area.

The State intends to establish a monitoring network to complement the monitoring required by the SIP and to provide additional background data. It will perform visual and photographic monitoring until additional funding can be obtained to begin installation of a continuous visibility monitoring network.

The Utah monitoring section of the Visibility SIP consists of a statement of goals, a list of monitoring methods, and a provision for future plan revisions. These provisions meet EPA criteria and EPA is proposing to approve this phase of the plan.

New Source Review

40 CFR 51.307 requires states to review new major stationary sources and major modifications prior to construction to assess potential impacts on visibility in any visibility protection area, regardless of the air quality status of the area in which the source is located. That is, sources locating in attainment areas and nonattainment areas must undergo visibility new source review (See 40 CFR 51.307(a) and (b)(2), respectively). These requirements ensure that (1) the visibility impact review is conducted in a timely and consistent manner, (2) the reviewing authority considers any timely FLM analysis demonstrating that a proposed source would have an adverse impact on visibility, and (3) public availability of the permitting authority's conclusion.

There are two parts to visibility NSR: PSD major stationary sources and major sources in nonattainment areas.

For all Major PSD Stationary Sources

(1) The State must notify the FLM in writing not more than 30 days after receiving a permit application or advance notification of application from a proposed source that may impact a visibility protection area.

(2) This notification must take place at least 60 days prior to the public hearing on the application and must contain any analysis of the potential impact of the proposed source on visibility.

(3) The State must consider any analysis concerning visibility impairment performed by the FLM and received not more than 30 days after the notification.

(4) If the State does not concur with the FLM's analysis that adverse visibility impairment will result from the proposed source, the State must provide in its notice of public hearing on the application an explanation of its decision or give notice as to where the explanation can be obtained.

(5) The State must have the ability to require a permit applicant to monitor visibility in or around the visibility protection areas.

For Major Sources in Nonattainment Areas

(1) A major source of modification that may impact a visibility protection area must provide a visibility impact analysis.

(2) The State must ensure that the sources' emissions are consistent with the national visibility goal. The State may consider the cost of compliance, the time for compliance, the energy and non-air quality environmental impacts of compliance, and the useful life of the source.

(3) The State must follow the same procedures outlined in the PSD items 1–5 above in conducting nonattainment area visibility reviews.

Items 1 through 5 for major PSD stationary sources and items 1 through 3 for major sources in nonattainment areas are the procedural steps in visibility review as defined in 40 CFR 51.307.

The Utah visibility SIP has incorporated into the NSR section its existing permit requirements for any source locating in an attainment or nonattainment area. The Utah Air Conservation Regulation (UACR) 3.1, Notice of Intent and Approval Order, specifies the standard requirements for

any permit application and permit approval.

The Visibility Regulation, UACR Section 3.11.1, provides for the Executive Secretary (Utah Bureau of Air Quality permit issuing authority) to consider any analysis performed by the State and the FLM and to deny a permit if the proposed source or modification would have adverse impact in any Federal Class I area. Further, UACR Section 3.11.1 conditions any permit issued under Section 3.1 in that the Executive Secretary will require the use of air pollution control equipments, technologies, methods, or work practices deemed necessary to mitigate visibility impact in Class I areas.

The SIP commits to the notification time frame requirements to the FLM. It commits to provide an explanation of its decision should it disagree with the FLM's assessment on a proposed source's impact on visibility and to give notice as to where that explanation can be obtained.

FLM Coordination

Under section 165(d) of the Clean Air Act, the FLM is given an affirmative responsibility to protect air quality related values, including visibility, in lands within a Class I area. The visibility regulations allow the FLM the opportunity to identify visibility impairment and to identify elements for inclusion in monitoring strategies. The FLM must maintain these areas consistent with congressional land use goals.

The State of Utah has accorded the FLM (through the National Park Service (NPS)) opportunities to participate and comment on its visibility SIP and regulations. Comments by the NPS were considered and incorporated where applicable. The State has committed in the SIP to consult continually with the FLM on the review and implementation of the visibility program. Further, the State recognizes the expertise of the FLM (i.e., the NPS) in monitoring and new source applicability analyses for visibility and has agreed to notify the FLM of any advance notification or early consultation with a major new or modifying source prior to the submission of the permit application.

Summary of action

The April 26, 1985 submittal by the Governor of Utah includes an adequate visibility plan and regulation to meet the requirements of 40 CFR 51.305 and 51.307 and the criteria discussed in 49 FR 42670. (One should reference the October 23, 1984, 49 FR 42670, for additional information). The SIP commits to an annual review and making any changes deemed necessary. The SIP, therefore, has established the commitment to review the visibility requirements listed in 40 CFR Part 51 Subpart P—Protection of Visibility. The SIP is still deficient for all the other requirements of Subpart P (except 51.305 and 51.307) which should be addressed within the proper timeframe after EPA promulgation or rulemking.

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

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

The Administrator's decision to approve or disapprove the plan revisions will be based on whether they meet the requirements of sections 110(a)(2)(A)–(K) and 110(a)(3) of the Clean Air Act, as amended. These revisions are being proposed pursuant to sections 110(a) and 301(a) of the Clean Air Act, as amended (42 USC 7410 (a) and 7601 (a)).

Authority: 42 U.S.C. 7401–7642.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur Oxides, Nitrogen Dioxide, Lead, Particulate Matter, Carbon Monoxide, and Hydrocarbons.

Dated: August 19, 1985

Irwin L. Dickstein,

Acting Regional Administrator.

[FR Doc. 85–26936 Filed 11–12–85; 8:45 am]

BILLING CODE 6560-50-M

---

40 CFR Part 435

[OW-FRL-2922-5]

Oil and Gas Extraction Point Source Category, Offshore Subcategory; Effluent Limitations Guidelines and New Sources Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period and notice of workshop on proposed regulations.

SUMMARY: EPA is scheduling a public workshop on proposed best available technology effluent limitations guidelines and new source performance standards for the offshore oil and gas industry that were published in the **Federal Register** on August 26, 1985 (50 FR 34592). EPA is also extending the original comment period on the proposed regulation.

DATES: The comment period for the proposed rule is extended by 30 days to end on January 15, 1986. A public workshop will be conducted on December 18, 1985 at the Copley Plaza Hotel, 138 St. James Avenue, Boston, Mass. There will be no preregistration. On-site registration will begin at 8:30 a.m. The workshop will be conducted from 9:00 a.m. to 4:30 p.m. local time.

FOR FURTHER INFORMATION CONTACT: Mr. Dennis Ruddy, Industrial Technology Division (WH–552), U.S. EPA, 401 M Street, SW, Washington, DC 20460, or call (202) 382–7131.

SUPPLEMENTARY INFORMATION: On August 26, 1985, EPA published best available technology effluent limitations guidelines and new source performance standards in the **Federal Register** for review and comment (50 FR 34592). The comment period began on September 16, 1985 and was to end on December 16, 1985. The Agency announced two public workshops to be held during the comment period. The purpose of the workshops is to present and discuss the provisions of the proposed regulations so that interested individuals would be better informed for the preparation of formal comments on the proposed regulations. The two announced workshops were conducted in New Orleans, Louisiana and Sanata Barbara, California.

The Agency recently received a request to schedule and conduct one additional workshop in the Northeastern United States to provide interested members of the public in the North Atlantic region an opportunity to participate in presentations and discussion on the proposed regulations. The Agency agrees that such a workshop would be beneficial to the public and to the rulemaking process. Accordingly, the Agency has scheduled one additional workshop to be conducted in Boston, Massachusetts on December 18, 1985. The comment period on the proposed regulations is extended by 30 days to end on January 15, 1986 (see DATES section above). This extension will provide time for development of written public comment by attendees of the additional workshop. The extension, however, will apply to all commenters.

Dated: October 31, 1985.

Lawrence Jensen,

Assistant Administrator for Water.

[FR Doc. 85–26931 Filed 11–12–85; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 796 and 799

[OPTS-42075; TSH-FRL 2904-2]

Pentabromoethylbenzene; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing that manufacturers and processors of pentabromethylbenzene (PEB, CAS No. 85-22-3) be required, under section 4 of the Toxic Substances Control Act (TSCA), to perform testing for chemical fate and environmental effects. This proposed rule is in response to the Interagency Testing Committee's (ITC's) designation of PEB for priority consideration for health and environmental effects testing.

DATES: Submit written comments on or before January 13, 1986. If persons request an opportunity to submit oral comment by December 30, 1985. EPA will hold a public meeting on this rule in Washington, D.C.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42075), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St., SW, Washington, D.C. 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW, Washington, D.C. 20460, Toll free: (801-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the ITC's designation of PEB for health and environmental effects testing consideration.

I. Introduction

A. ITC Recommendation

TSCA (Pub. L. 94-469, 90 Stat. 2003 et seq.; 15 U.S.C. 2601 et seq.) established the ITC under section 4(e) to recommended to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated PEB (CAS No. 85-22-3) for priority consideration in its 15th Report, which was submitted to EPA on November 6, 1984. The report was published in the **Federal Register** of November 29, 1984 (49 FR 46931). The ITC recommended that PEB be considered for health effects testing, including chronic effects and teratogenicity, and ecological effects testing, including acute and chronic toxicity to fish, aquatic invertebrats, and plants. The ITC's rationale for health effects testing includes the following: (1) Releases from production and use are expected to result in human exposure, and (2) there is insufficient information on the chronic effects of PEB and toxic effects are observed in compounds having a polyhalogenated aromatic moiety. The chronic bioassay was recommended rather than short-term tests because the latter do not, in general, show a positive association with carcinogenicity for polyhalogenated compounds. Teratogenicity testing was recommended because of lack of information.

The ITC's rationale for ecological effects testing includes the following: (1) PEB maybe widely distributed in the environment; (2) PEB is structurally similar to halogenated compounds that have appreciably toxicity; (3) PEB is expected to partition into soils, sediments, and biota after release; and (4) data on a structurally related compound, pentabromomethylbenzene, indicate that although only low levels of PEB may be taken up by aquatic organisms, its residence time in the organisms may be relatively long. The ITC regarded this as presumptive evidence that PEP may have the potential to produce chronic effects.

B. Test Rule Development Under TSCA

Under section 4(a) of TSCA, EPA shall by rule require testing of a chemical substance or mixture to develop appropriate test data if the Administrator finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, many present an unreasonable risk of injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in making a section 4(a)(1)(A)(i) finding; both exposure and toxicity information are considered in determining whether available data support a finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure, and release information to determine whether there is or may be substantial production and significant or substantial human exposure or substantial release to the environment. For the findings under sections 4(a)(1) (A)(ii) and (B)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the finding under section 4(a)(1) (A)(iii) or (B)(iii) that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules as published in the **Federal Register** of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300). The seciton 4(a)(1)(A) findings are discussed at 45 FR 48524 and 46 FR 30300, and the seciton 4(a)(1)(B) findings are discussed at 46 FR 30300.

In evaluating the ITC's testing recommendations for PEB, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration and any public comments on the ITC's recommendations; production volume, use, exposure, and release information reported by manufacturers of PEB under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); health and safety studies submitted

under the TSCA seciton 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716) for PEB; and published and unpublished data available to the Agency. Its evaluation, as described in this proposed rule, leads EPA to propose chemical fate and environmental effects testing requirements for PEB under section 4(a)(1)(A). By this action, EPA is responding to the ITC's designation of PEB for priority testing consideration.

II. Review of Available Data

A. Production

According to the public portion of the TSCA inventory, 1977 production of PEB was 100,000 to 1 million pounds. The public portion of the 1977 TSCA Inventory lists Velsicol Chemical Corp., St. Louis, MO; Great Lakes Chemical Corp., El Dorado, AR and West Lafayette, IN; Hexcel/Fine Organics, Sayreville, NJ; and the Chemical Systems Lab, Aberdeen Proving Grounds, MD as producers of PEB. Neither Great Lakes Chemical Corp. nor Velsicol Chemical Company presently produce PEB (Refs. 1 and 2). The U.S. International Trade Commission listed Ethyl Corp. as the only domestic producer of PEB from 1980 to 1983 (Refs. 3 through 6). Ethyl Corp. currently produces PEB and plans to continue PEB production through 1985 (Ref. 7). Ethyl Corp. submitted production volumes for 1980–1984 and export volumes for 1984 as confidential business information (CBI) (Refs. 8 and 9).

PEB can be prepared in an inert solvent by a Friedel-Crafts catalyzed bromination of ethylbenzene (Ref. 10). Batch processes are used by Ethyl Corp. (Ref. 7) to prepare the compound. Ethyl Corp. (Refs. 7 and 11) packages PEB in 250-lb. capacity fiber drums.

B. Uses

PEB is an additive-type flame retardant (1 to 8 percent w/w) and is suggested for use in thermoset polyester resins for circuit boards, textiles, adhesives, wire and cable coatings, polyurethanes, and thermoplastic resins (Refs. 7, 11, 12, and 13). Ethyl Corp. (Ref. 13) stated that it knew of no PEB uses in any consumer products. They were also unaware of any non-flame retardant PEB uses. According to Ethyl Corp., probable uses by its current customers for PEB as a flame retardant are in adhesives, polyester resins, textiles, and polyurethane foam (Ref. 14). Ethyl Corp. has submitted domestic customer sales volumes, number of U.S. customers, and geographical location of U.S. customers for 1984 as CBI (Refs. 8, 9, and 15).

C. Exposure and Release

Ethyl Corp. (Ref. 13) reported that an analytical method specific for the quantitation of PEB was not available to them. The total dust concentration is, therefore, the only available measure of the compound's concentration in workplace air. Ethyl Corp. (Ref. 13) has reported personal monitoring for total dust of a packer in the PEB packaging area. The result was <1 mg/m^3 with limits of detection being 1 mg/m^3 to 2 mg/m^3. OSHA has established limits for nuisance dust of 5 mg/m^3 for respirable fractions and 15 mg/m^3 for total dust (Ref. 16).

Ethyl Corp. (Refs. 8 and 13) submitted worker exposure estimates. During PEB production, one worker per day will be exposed to PEB while digging the product from a nutsche filter (Ref. 13). One operator per shift will be exposed during packaging (Ref. 13). During production, workers are required by Ethyl Corp. to wear body-covering clothing, safety shoes, safety glasses/goggles, gloves, a safety helmet and a respirator (Ref. 13). Packaging operators must also wear this equipment plus a dust cap and disposable coveralls and booties (Ref. 13). Mechanical ventilation is used to limit exposure to PEB by packagers (Ref. 13). Ethyl's Material Safety Data Sheet recommends that protective equipment and clothing be worn when handling PEB (Ref. 16).

Ethyl Corp. (Ref. 13) reports that manufacturing wastes are disposed of at an off-site landfill. Specifically, PEB is disposed of in 55-gallon sealed metal drums, and still bottoms from recycling process solvent are disposed of as waste-flammable liquid, not otherwise specified, EPA Waste No D001 (Ref. 13). Ethyl Corp. has submitted as CBI the amount of these untreated PEB manufacturing wastes (Ref. 8). Ethyl Corp. recommends on its Material Safety Data Sheet to dispose of waste PEB in a "chemically secure" landfill (Ref. 17).

Several possible point sources of PEB release into the environment occur during manufacturing and packaging (Ref. 13). To minimize worker exposure to dust, the packaging of PEB is performed in well-ventilated buildings. Intervening between these buildings and the atmosphere are bag houses designed to collect dust. No information on the efficiency of these bag houses was given. Ethyl Corp. has submitted as CBI estimates of the amount of PEB lost to the environment (Refs. 8 and 9).

According to Ethyl Corp. (Ref. 13), PEB crystals are washed with water during separation from the mother liquor. The wastewater is discharged into a sewer system and ultimately treated at a publicly-owned treatment works (POTW). It is possible, therefore, that PEB may be released to the aquatic environment and that aquatic organisms may be exposed to PEB. No information on PEB levels in this water was given. However, the low water solubility of PEB suggests that most of the PEB not degraded in the POTW would be adsorbed onto the sludge and not be released in the effluent. The sludge from this particular POTW is dumped into the ocean at a site 12 miles directly off the Southern New Jersey Coast (Ref. 18). In the near future, a site 106 miles out will be used (Ref. 18). Ethyl Corp. has submitted domestic sales volumes, number of U.S. customers and geographical locations of U.S. customers for 1984 as CBI (Refs. 8, 9, and 15). However, information is not available to EPA concerning the quantities of PEB released from these processing sites.

In summary, EPA concludes that based on the available data, human exposure to PEB will be quite limited. However, there is evidence that small quantities of PEB are released to the environment as a result of manufacturing and additional amounts of PEB (which cannot be quantified at this time) can be expected to be released to the environment from processing activities.

D. Health Effects

1. *Pharmacokinetics.* Very few data on the absorption, distribution, metabolism, and elimination of PEB were located in the available literature. In a 28-day feeding study, PEB was administered to male and female Charles River CD rats at 100 and 1,000 ppm (corresponding to 5 and 50 mg/kg bw/day assuming that a rat consumes 0.05 kg food/kg bw/day) in the diet (Ref. 19). At the end of the study, the bromine content of the liver and fat was elevated in a dose-related manner (see Unit II.D.3) indicating absorption of the compound when exposure occurs by the oral route.

2. *Acute toxicity*—a. *Oral Studies.* In a study conducted by Industrial Bio-Test Laboratories in 1976 (Ref. 20), an oral LD_{50} was calculated to be 6,800 mg/kg (range 5,271–8,722 mg/kg), which led these authors to classify PEB as "practically non-toxic."

Great Lakes Chemical Company (Ref. 21) provided data on a study in which PEB as a suspension in corn oil was administered by gavage to male Carworth CFE rats (five/dose level). The dosages employed were 50, 500, and 5,000 mg/kg bw. Normal weight gains

were recorded for all exposed rats during the 14-day observation period.

b. *Inhalation Studies.* Carworth CFE rats (10 males/group) were exposed to two dose levels of PEB dust in air for 1 hour and were observed for 14 days following the single exposure (Ref. 21). Addition of the PEB dust to the atmosphere in the test chamber was controlled by a Wright Dust Feeder. The atmospheric concentrations administered were calculated to be approximately 2 and 200 mg PEB/1 air (2,000 and 200,000 mg/m^3, 97.6 and 9,760 ppm). No deaths were reported at either exposure level. Symptoms such as eye squint, changed respiratory rates, prostration, salivation, lacrimation, erythema, and decreased motor activity were noted at both exposure levels during the treatment periods. At 2 mg/l (97.6 ppm) the animals exhibited complete recovery within 24 hours. No additional symptoms were noted over the 14-day observation period. At 200 mg/l (9,760 ppm) dyspnea was also observed. Decreased motor activity persisted throughout the 9th day. Corneal opacity, chemosis, and drying of the corneal surface persisting through the 9th day were also observed. Corneal opacity was reported in one rat on the 10th and 11th day and in one rat on the 14th day. It was not specifically stated whether the same rat was involved each time.

Industrial Bio-Test performed a heated vapor inhalation toxicity study of PEB in which five male and five female Charles River rats were exposed to 0.57 mg PEB/1 air for 4 hours and were subsequently observed for a 14-day period (Ref. 22). The report did not provide any indication of the method of measuring the vapor concentration of PEB. Normal weight gains were reported for all animals. Necropsies performed at the end of the observation period did not reveal any gross pathologic changes.

c. *Dermal Studies.* Industrial Bio-Test applied PEB (3,000 mg/kg) as a slurry in 3 percent (w/v) aqueous methylcellulose to the shaved skin of four New Zealand white rabbits (two males and two females) (Ref. 20). The skin of one animal of each sex was abraded. The application site was covered by securely taped impervious plastic sheeting for 24 hours, at which time the bandages and the residual test material were removed. No deaths occurred during the 14-day observation period. At 24 hours pale red erythema was noted in the treated areas and was still observable at 7 days. At 14 days, it was barely perceptible, and mild desquamation was noted. No gross pathologic changes were noted upon necropsy at 14 days.

Great Lakes (Ref. 21) employed two dosage levels of PEB (200 and 2,000 mg/kg) in a similar experimental protocol using two males and two female New Zealand white rabbits at each dose level. No deaths occurred during the 14-day observation period. One animal at each dose level lost weight, but this was attributed to injuries received during the experiment and was not considered compound related.

Ethyl Corp. (Ref. 23) reported the dermal LD_{50} of PEB in the New Zealand white rabbit to be $>8,000$ mg/kg (the highest dose mechanically feasible); however, no further information was provided.

Great Lakes (Ref. 21) performed skin irritation tests using three male and three female New Zealand white rabbits. The clipped skin of three of the animals was abraded with a scalpel blade. PEB (500 mg/animal) was applied as a grainy powder and was covered for 24 hours by occlusive bandages, after which the bandages and residual test material were removed. The sites were examined and scored for evidence of irritation at 24 and 72 hours. No edema was observed in any test animals. Erythema was noted in one animal with intact skin and one which abraded skin at 24 hours. No erythema was observed at 72 hours. The author concluded that PEB was not a primary skin irritant. In similar tests Industrial Bio-Test classified PEB as moderately irritating (Ref. 20).

d. *Eye irritation.* Great Lakes (Ref. 21) commissioned an eye irritation test using three male and three female New Zealand white rabbits. Slight to moderate conjunctival redness was observed in five of the six animals at 24 hours. This persisted throughout the 7-day observation period. Very slight chemosis was seen in one animal at 24 and 48 hours, but was not noted at later examinations. No discharge was observed in any of the test animals. The investigators considered PEB a possible slight eye irritant. In similar tests Industrial Bio-test classified PEB as minimally irritating to rabbit eyes (Ref. 20).

Ethyl Corp. (Ref. 24) performed an eye irritation study in an unspecified animal (probably the rabbit) according to standard techniques in which 100 mg of PEB as a powder was applied to the eye. The treated eyes were left unwashed and were observed at 1, 2, 3, 4, and 7 days after treatment. No irritation or corneal damage was noted in treated or untreated eyes. No further experimental details were provided.

e. *Other acute studies.* Limited data are available on the effects of parenteral administration of PEB. In a preliminary report on the effects of four times retardants on liver microsomal enzyme systems, an unquantified decrease in the N-demethylation of ethylmorphine was observed after mice were treated with unspecified levels of PEB (by intraperitoneal injection) daily for 3 days (Ref. 25).

3. *Subchronic toxicity.* Great Lakes (Ref. 19) administered PEB to male and female Charles River CD rats at 0, 100, and 1,000 ppm in the diet (10 animals/sex/dose level) for 28 days. Animals were killed and selected organs were weighted. The livers, kidneys, and thyroids were examined microscopically. Liver and fat specimens were analyzed for bromine content. No compound-related changes in behavior or appearance were observed throughout the course of the study. Male rats at both dose levels consumed less food and gained less weight than control animals. The bromine content of the liver and fat was evaluated for all treated groups. Bromine content of the livers of control rats was 2.3 ppm for males and 4.9 ppm for females. Male and female animals that received 100 ppm PEB in the diet had 5.2 and 5.5 ppm bromine, respectively, in their livers; at 1,000 ppm PEB in the diet, they had 24.2 and 40.4 ppm bromine in their livers. Control values for bromine in the fat were 1.0 ppm in males and 1.3 ppm in females. At 100 ppm PEB in the diet, males had 7.7 and females had 7.1 ppm bromine in the fat. The values were 75.5 and 61.9 ppm, PEB in the diet. No compound-related gross or microscopic pathologic lesions were observed at necropsy in any of the treated animals.

At the request of Hexcel-Fine Organics Division, Consumer Product Testing Co. performed a skin sensitization study in guinea pigs using a 0.1-percent suspension of PEB in physiological saline (Ref. 26). PEB was injected intradermally into 10 white male guinea pigs, 10 times over a 21-day period (every other day). The first injection consisted of a volume of 0.05 ml; the other 9 injections were of 0.1 ml each. Two weeks following the tenth injection a retest injection of 0.05 ml was made. Injection sites were examined and scored for the diameter, height, and color of the reaction 24 hours after each injection. Irritation was observed in all animals during the sensitization period following the third injection. One animal died during this period, but the report states that the death was not compound related. No reaction was seen in any animal following the challenge dose. PEB was not considered to be a sensitizing

material to guinea pigs under the conditions of this test.

Ethyl Corp. (Ref. 23) also performed a 21-day dermal toxicity study of PEB using 30 New Zealand white rabbits (15 males and 15 females). PEB (0, 4, or 8 g/kg bw) was applied as a powder to clipped or clipped and abraded skin. The powder was held in place with gauze and adhesive tape for a 6-hour application period, after which the powder was brushed from the sites. Applications were made daily for 21 consecutive days. Hematological, blood chemistry, and urinalysis studies were performed prior to the beginning of dosing and after the 21st application of PEB. A complete necropsy was performed on the 28 animals that were killed following the completion of the study and on the 2 that died (from causes determined to be not treatment related) during the course of the study. Animals showed an apparent dose-related decrease in weight gain (controls gained 0.28 kg in 21 days; animals dosed with 4 g PEB/kg body weight gained 0.13 kg; and animals dosed with 8 g/kg gained 0.07 kg); however, the experimenter was unable to determine whether this observation was compound-related or was caused by the increased handling of the treated animals. No dermal irritation was seen in any animal in any treatment group at any time throughout the course of the study. No treatment related effects were observed in the hematologic, blood chemistry, or urine analyses. No treatment-related effects were observed upon necropsy or histopathological examination.

4. *Chronic toxicity.* No chronic toxicity data for PEB were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

5. *Developmental and reproductive toxicity.* No developmental or reproductive toxicity data for PEB were located in the available literature or were reported under TSCA section 8(d) (49 FR 46741) for this chemical.

A teratological evaluation of a structurally related compound, pentabromomethylbenzene (PMB), is available in abstract form (Ref. 27). The compound was administered orally to rats on gestational days 6 through 15 at 0, 7.5, 150, 300, and 600 mg/kg bw/day. No significant effect of the treatment was noted in any of the parameters studied. These parameters included maternal weight gain, maternal hemotology and serum biochemistry, litter size, fetal weight, deciduoma, fetal skeletal and visceral abnormalities, and miscroscopic tissue changes.

6. *Mutagenicity.*—a. *Gene mutation studies.* Pentabromoethylbenzene has been tested for mutagenicity in *Salmonella typhimurium* and *Saccharomyces cerevisiae* (Refs. 28 and 29). In both studies *Salmonella* strains TA1535, TA1537, TA1538, TA98, and TA100 and *Saccharomyces* strain Dr were employed in a plate incorporation assay both with and without metabolic activation. In one study (Ref. 28), concentrations of PEB were employed ranging from 0.05–50)g/plate. In the other study (Ref. 28), six concentrations (from 0.1–5,000)g/plate) were used. The results of the tests were all negative and PEB was judged to be nonmutegenic under these conditions.

NTP (Ref. 30) performed a series of tests using *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100. PEB in dimethylsulfoxide (0, 333, 1,000, 3,333, 6,666, or 10,000)g/plate) was tested with or without activation by S–9. The results were uniformly negative under these conditions.

b. *Chromosomal aberration studies.* No data on the ability of PEB to cause cytogenetic damage were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

c. *Other studies indicative of genetic damage.* No other data on the ability of PEB to cause genetic damage were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

7. *Oncogenicity.* No data on the oncogenicity of PEB in animals or humans were located in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

E. Chemical Fate

1. *Water solubility and octanol/water partition coefficient.* A water solubility of 3.98×10^{-3} mg/1 (3.98 ppb) and a log of the octanol/water partition coefficient (log P) of 7.63 have been calculated for PEB (Ref. 31). These values indicate that under equilibrium conditions, PEB will partition primarily into the soil/sediment compartment.

2. *Soil mobility.* The sorption properties of PEB to soil have not been reported in the available literature. However, using equations developed by Lyman et al. (Ref. 32) a value for the soil-sorption coefficient (K_{oc}) of 7.42 has been calculated (Ref. 31) for PEB from its calculated log P of 7.63 (Ref. 31). This estimate of log K_{oc} indicates that PEB will substantially partition to organic matter in soil and sediment and be highly immobile in these media.

3. *Persistence.* EPA is not aware of any information on the environmental persistence of PEB in the available literature. The structure of PEB suggests, by analogy to other halogenated aromatic compounds, that PEB might be extremely persistent, with the aromatic part of the molecule highly resistant to biodegradation and chemical attack. However, the aliphatic side chain could be biodegraded.

F. Environmental Effects

1. *Bioconcentration.* No data were found in the available literature on the bioconcentration of PEB in adquatic organisms. Using the equation (log BCF = 0.85 log P − 0.70) developed by Veith (Ref. 33), the log of the bioconcentration factor (log BCF) for PEB estimated from its log P value is 5.79. This estimate indicates that PEB may bioconcentrate to a significant degree.

A structurally related compound, pentabromomethylbenzene (PMB), in a study with juvenile Atlantic Salmon (Ref. 34), exhibited a fairly low uptake from water (96 hours) and from food (42 days). Depuration half-lives were 32 and 83 days for uptake from water and food, respectively. It should be noted that 96 hours is a fairly short time for evaluating chemical uptake from water, and that an extended period of testing might have resulted in much higher accumulation. The relatively long depuration half-lives also create some concern for potential chronic effects.

2. *Acute and chronic effects on fish, aquatic invertebrates, and plants.* No data were located on PEB in the available literature or were reported under the TSCA section 8(d) rule (49 FR 46741) for this chemical.

III. Findings

A. Health Effects

Ethyl Corp. has submitted to EPA occupational exposure information, production volumes for 1980–1984, export data for 1984, and sales volumes to its domestic customers for 1984 as CBI (Refs. 8, 9 and 15). On the basis of this information EPA concludes that a section 4(a)(1)(B) finding for health effects cannot be supported because of lack of substantial production and because human exposure to PEB is neither significant nor substantial. Furthermore, EPA concludes that the current exposures to PEB, taken together with the existing health effects data discussed in Unit II.D of this notice, do not provide a basis for a section 4(a)(1)(A) finding under TSCA. However, EPA is considering an appropriate followup activity to monitor future increased production or use of

PEB. Should such increases occur, EPA would reconsider the need to propose health effects testing of PEB.

B. Chemical Fate and Environmental Effects

In the area of chemical fate and environmental effects testing, EPA is making a section 4(a)(1)(A) finding.

The section 4(a)(1)(A) findings for chemical fate and environmental effects are as follows:

EPA finds that the manufacture, processing, and disposal of PEB may present an unreasonable risk of injury to the environment because PEB is potentially persistent, PEB may bioconcentrate, and there is potential for release of PEB to the environment.

EPA also finds that there are insufficient chemical fate and environmental effects data to reasonably determine or predict the chemical fate and environmental effects of such PEB releases. The finding of potential unreasonable risk is based on two considerations: (1) The structure of PEB suggests by analogy to other halogenated aromatic compounds that PEB might be extremely persistent. PEB's structure suggests that most of the molecule will be highly resistant to biodegradation and chemical change. Although the ethyl group offers a potential point of attack by microorganisms, only testing can resolve the question of degradability. (2) PEB's estimated log P suggests that PEB may bioconcentrate to a significant degree. Pentabromomethylbenzene (PMB), structurally related to PEB, appears to be poorly absorbed in juvenile Atlantic salmon, but once taken up it is excreted very slowly. PEB may respond similarly. Therefore, because PEB may bioconcentrate and because a structurally related compound shows potential for bioconcentration, EPA is proposing such testing.

EPA finds that additional chemical fate and environmental effects testing of PEB is necessary to develop data to evaluate the chemical fate and environmental effects of PEB. Because wastewater from PEB manufacture goes to a POTW and EPA has no information on concentrations of PEB entering or leaving the POTW, testing is necessary to determine whether PEB entering treatment is completely removed by degradation and absorption onto sludge, or whether POTW effluent may still contain PEB that may pose a risk to aquatic life. EPA encourages manufacturers and processors to submit any available data or to monitor POTW influent and effluent as well as sludge PEB concentrations. Such information could be useful to EPA in determining the need for chemical fate and environmental effects testing.

EPA is not proposing testing in aquatic plants, algae, or pelagic fish because, on the basis of PEB's extremely low water solubility and high sediment sorption coefficient, the Agency believes PEB would partition to the organic phase of sediment and to lipids in biological tissues and that a benthic organism such as the oyster provides a better test organism to assess the aquatic toxicity and bioconcentration potential of PEB.

IV. Proposed Rule

A. Proposed Testing and Test Standards

On the basis of the findings given above for chemical fate and environmental effects testing (see Unit III.B), the Agency is proposing chemical fate and environmental effects testing of PEB. Test methods under new parts 796 and 797 of 40 CFR were published in the **Federal Register** of September 27, 1985 (50 FR 39252). Initial testing would consist of chemical fate testing to determine whether PEB would be released to the aquatic environments and be persistent in soil environments. The initial tests are (1) water solubility, (2) semicontinuous activated sludge biodegradation and physical removal adsorption on sludge and (3) inherent biodegradability in soil. The Agency is proposing that PEB be tested for water solubility using the test specified in 40 CFR 796.1860. Although EPA has estimated PEB's water solubility (see Unit II.E.1), the Agency considers it necessary that an experimentally determined water solubility be obtained for this compound because this information is necessary before other tests on PEB can be conducted. The Agency is proposing that PEB be tested for semicontinuous activated sludge biodegradation and physical removal by adsorption on sludge using the test specified in 40 CFR 796.3341. The Agency is proposing that PEB be tested for inherent biodegradability in soil using the test specified in 40 CFR 796.3400.

The semicontinuous activated sludge and physical removal by adsorption test will allow EPA to evaluate whether releases of PEB to waste water treatment facilities will be removed by such treatment or will potentially be released to the aquatic environment. The Agency is proposing that if any PEB is found in the aqueous phase in the semicontinuous activated sludge and physical removal by adsorption test specified in 40 CFR 796.3341, the following three tests be conducted: (1) Biodegradation rate using the protocol described in a study by Bourquin et al. (Ref. 35); (2) acute aquatic toxicity in benthic organisms (oyster) using the test specified in 40 CFR 797.1800; (3) bioconcentration in benthic organisms using the test specified in 40 CFR 979.1830.

The Agency is proposing that the above referenced TSCA Chemical Fate and Environmental Effects Test Guidelines and other cited methods be considered the test standards for the purposes of the proposed tests for PEB. The TSCA guidelines for chemical fate and aquatic toxicity testing specify generally accepted minimal conditions for determining chemical fate and aquatic animal toxicities for substances like PEB to which aquatic life is expected to be exposed. The Agency's review of the guidelines, which occurs on a yearly basis as described in 47 FR 41857 (September 22, 1982), has found no reason to conclude that these protocols need to be modified significantly except for the protocol for the semicontinuous activated sludge test. Modifications to this test are necessary because of PEB's limited water solubility. Additionally, the test procedure employed by Bourquin et al. (Ref. 35) specifies, in EPA's judgment, minimal test conditions and practices for acceptable investigations of PEB's rate of biodegradation. Although the Agency has not issued a TSCA testing guideline for biodegradation rate, the testing procedures found in this reference reflect the current state of the science for such testing and is being proposed as an acceptable method for testing PEB's biodegradation rate.

EPA intends to propose shortly in a separate **Federal Register** notice, certain revisions to these TSCA Test Guidelines to provide more explicit guidance on the necessary minimum elements for each study. These revisions will avoid repetitive chemical-by-chemical changes to the guidelines in their adoption as test standards for chemical-specific test rules. EPA is proposing that these modifications be adopted in the test standards for PEB.

B. Test Substance

EPA is proposing that PEB of at least 95 percent purity be used as the test substance; EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to PEB itself. Commercial PEB is 95 percent pure.

C. Persons Required To Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Agency

makes section 4(a) findings (manufacture, processing, distribution, use and/or (disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the findings are based on distribution, use, or disposal.

Because EPA has found that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, processing and disposal of PEB on the environment, EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, PEB at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements contained in this proposed rule. The end of the reimbursement period will be 5 years after the last final report is submitted.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

When both manufacturers and processors are subject to a test rule, EPA expects that manufacturers will conduct the testing and that processors will ordinarily be exempted from testing. As described in 40 CFR Part 790, processors will be be granted an exemption automatically without filing applications if manufacturers perform all of the required testing. Manufacturers are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the test rule.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for PEB. As noted in Unit IV.B, EPA is interested in evaluating the effects attributable to PEB itself and has specified a relatively pure substance for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

D. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) standards, which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 30 days prior to the initiation of each study.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is proposing specific reporting requirements for each of the proposed test standards as follows:

1. The water solubility test, semicontinuous activated sludge and physical removal by adsorption test, and the inherent biodegradability in soil test shall be completed and the final results submitted to EPA within 1 year of the effective date of the final test rule. Quarterly progress reports shall be submitted beginning 90 days after the effective date of the final rule.

2. The biodegradation rate test, acute aquatic toxicity in oyster test, and bioconcentration in oyster test shall be completed and the final results submitted to EPA within 2 years of the effectie date of the final test rule if triggered by results from the semicontinuous activated sludge and physical removal by adsorption test. Quarterly progress reports shall be submitted beginning 120 days after submission of study plans for these tests.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the **Federal Register** as required by section 4(d).

Persons who export a chemical substance or mixture which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707 (45 FR 82844; December 16, 1980). In brief, as of the effective date of the final test rule, an exporter of PEB must report to EPA the first annual export or intended export of PEB to an one country. EPA will notify the foreign country about the test rule for the chemical.

E. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records; (2) submit reports, notices, or other information; or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce . . . ." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for PEB. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaulations, and to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of the TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adqequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who

violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in TSCA section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

V. Issues For Comment

This proposed rule specifies TSCA test guidelines and independent, published test methods as the test standards for environmental effects and chemical fate testing of PEB. The Agency is soliciting comments as to whether the chemical fate and environmental effects test guidelines and the independent methods are appropriate and applicable for the testing of PEB. Also regarding testing the of PEB, the Agency requests comments on:

1. The adequacy of this testing.
2. The reporting times for the identified chemical fate and environmental effects tests.
3. Whether there are any other testing approaches which should be considered.

VI. Economic Analysis of Proposed Rule

To assess the economic impact of this rule, EPA has prepared an economic analysis that evaluates the potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of PEB: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations.

Total testing costs for the proposed rule for PEB are estimated to range from $22,396 to $68,602. This estimate includes the costs for both the required minimum series of tests as well as the conditional tests. The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from $5,803 through $17,776. The cost of the first tier of testing ranges from $15,646 to $42,102, or only $2,137 to $6,669 on an annualized basis. There should be no adverse economic impact from the first tier tests. Based on the 1984 production volume reported under section 8(a) of TSCA (CBI), and the current list price for PEB of $2.35 per pound, the annualized total test cost for both the first and second tier tests could represent a significant impact on PEB as a percent of sale price. This conclusion is based on the following observations: (1) The annual unit cost of the testing required in this rule is high relative to expected revenue; (2) the market for PEB appears to be declining; and (3) the likelihood of substitutes among brominated flame retardants indicates that demand for PEB is relatively elastic with respect to price. Therefore, EPA tried to minimize any adverse economic impact by proposing tiered testing requirements and initial tests that are few and inexpensive. Testing beyond this limited first tier may not be necessary. Should the second set of testing be triggered from the results of the semicontinuous activated sludge and physical removal by absorption test, EPA concludes that the importance of the potential adverse enivronmental effects outweighs the possible adverse economic effects.

Refer to the economic analysis, which is available in the public record for this rulemaking (docket number OPTS–42075), for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

VII. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service (NTIS) (PB 82–140773) in Springfield, VA. On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this proposed rule.

VIII. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting in Washington, D.C. after the close of the public comment period. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free (800–424–9065); in Washington, D.C. (554–1404); outside the U.S.A. (Operator—202–554–1404), by December 30, 1985. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

IX. Public Record

EPA has established a record for this rulemaking, (docket number OPTS–42075). This record contains the basic information considered by the Agency in developing this proposal and appropriate **Federal Register** notices. The Agency will supplement this record with additional information as received.

This record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of pentabromoethylbenzene to the Priority List (49 FR 46931; November 29, 1984).

(b) Rules requiring TSCA section 8(a) and (d) reporting on pentabromoethylbenzene (49 FR 46739, 49 FR 46741; November 28, 1984).

(c) Notice containing TSCA test guidelines as test standards for this rule.

(d) Notice of final rulemaking on data reimbursements (48 FR 31786; July 11, 1983).

(e) Notice of final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(f) TSCA GLP Standards (48 FR 53922; Nov. 29, 1983).

(2) Support document consisting of pentabromoethylbenzene economic analysis.

(3) Communications before proposal consisting of:

(a) written public comments and letters.

(b) Contract reports of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished factual materials.

B. References

(1) Nametz, R. Great Lakes Corp., West Lafayette, IN 47906. Transcribed telephone conversation with S. Beals, Syracuse Research Corp., Syracuse, NY 13210. February 15, 1985.

(2) Velsicol Chemical Corp., Chicago, IL 60611. Letter from A.A. Levin to M. Greif, TSCA Interagency Testing Committee, Washington, D.C. 20460. Nov. 14, 1983.

(3) USITC. U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1980. Publication No. 1183. U.S. Government Printing Office. Washington, D.C. 1981.

(4) USITC, U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1981. Publication No. 1292. U.S. Government Printing Office, Washington, D.C. 1982.

(5) USITC, U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1982, Publication No. 1422. U.S. Government Printing Office, Washington, D.C. 1983.

(6) USITC. U.S. International Trade Commission. Synthetic Organic Chemicals, United States Production and Sales, 1983. Publication No. 1588. U.S. Government Printing Office, Washington, D.C. 1984.

(7) Ethyl Corp. Baton Rouge, LA, 70801. Letter and enclosures from R.L. Smith to M. Greif, TSCA Interagency Testing Committee, Washington, D.C. 20460. February 1, 1984.

(8) Ethyl Corp. Baton Rouge, LA 70898. 8(a) submission 80823950 Confidential Business Information. February 27, 1985.

(9) Ethyl Corp. Baton Rouge, LA 70898. Letter to J. Harris, Test Rules Development Branch, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C 20460. Confidential Business Information. DC No. 40-8560069. February 7, 1985.

(10) Kirk-Othmer. Kirk-Othmer Encyclopedia of Chemical Technology. 3rd ed. Vol. 10. John Wiley and Sons, Inc. New York. p. 384-387. 1980.

(11) Chemcyclopedia. The Annual Manual of Chemicals. VI. An American Chemical Society Publication. p. 124-125. 1982-1983.

(12) Ethyl Corp. Technical bulletin: Saytech flame retardants. Ethyl Tower, 451 Florida Blvd., Baton Rouge, LA 70801. n.d.

(13) Ethyl Corp. Baton Rouge, LA 70898. Letter (with CBI deleted by Ethyl Corp.) to J. Harris, Test Rules Development Branch, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 20460. February 7, 1985.

(14) Ethyl/Saytech. Sayreville, NJ 08872. Letter to J. Harris, Test Rules Development Branch, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 20460. March 15, 1985.

(15) Ethyl/Saytech. Sayreville, NJ 08872. Letter to Document Control Officer, Environmental Protection Agency, Washington, D.C. 20460. Pentabromoethylbenzene: 1984 sales volumes. Confidential Business Information: Document Control No. 40-8500075. March 15, 1985.

(16) OSHA Safety and Health Standards. 29 CFR 1910 1910.1000 Table Z-3. U.S. Dept. of Labor, OSHA. Revised. June 1981.

(17) Ethyl Corp. Ethyl Tower 451 Florida Blvd., Baton Rouge, LA 70898. Saytex 105: Material Safety Data Sheet. May 4, 1984.

(18) Mr. Aiello. Middlesex County Utilities Authority, Sayreville, NJ 08872. Transcribed telephone conversation with J. Robinson, Syracuse Research Corp., Syracuse, NY 13210. May 9, 1985.

(19) Great Lakes Chemical Corp. West Lafayette, IN 47906. TSCA sec. 8(d) submission 878214933. Twenty-eight day toxicity study in rats. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1985.

(20) Velsicol Chemical Corp. Chicago, IL 60611. TSCA sec. 8(d) submission 878214892. Acute toxicity studies with pentabromoethylbenzene. 1976. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1984.

(21) Great Lakes Chemical Corp. West Lafayette, IN 47906. TSCA sec. 8(d) submission 878214931. Acute toxicity studies in rats and rabbits. Pentabromoethylbenzene, 1973. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1985.

(22) Velsicol Chemical Corp. Chicago, IL 60611. TSCA sec. 8(d) submission 878214891. Acute heated vapor inhalation toxicity study with pentabromoethylbenzene in rats, 1976. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1984.

(23) Ethyl Corp. Baton Rouge, LA 70898. TSCA sec. 8(d) submission 878214943. Twenty-one day dermal toxicity study on rabbits, 1976. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1985.

(24) Ethyl Corp. Baton Rouge, LA 70898. TSCA sec. 8(d) submission 878214942. Eye irritation study. Assay No. 174-185, 174-186, 1975. Office of Toxic Substances, U.S. Environmental Protection Agency. , Washington, D.C. 1985.

(25) Lundberg, P. Effects of some flame retardants on the liver microsomal enzyme system. In: Microsomes, drug oxidation, and chemical carcinogenesis [4th Int. Symp. Microsomes Drug Oxid.] Coon MJ, ed. Vol. 2:853-856. 1980.

(26) Ethyl Corp. Baton Rouge, LA 70898. TSCA sec. 8(d) submission 878214941. Guinea pig sensitization: pentabromoethylbenzene, 1976. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1985.

(27) Ruddick, J.A., Black, W.D., Villeneuve, D.C., Valli, V.E. "A teratological evaluation of pentachlorotoluene and pentabromotoluene following oral treatment in the rat. (Abstract)." *Teratology* 29(2):56A. 1984.

(28) Velsicol Chemical Corp. Chicago, IL 60611. TSCA sec. 8(d) submission 878214893. Mutagenicity evaluation of 859-74-8. Final report, 1976. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1984.

(29) Great Lakes Chemical Corp. West Lafayette, IN 47906. TSCA sec. 8(d) submission 878214932. Mutagenicity evaluation of pentabromethylbenzene, 1977. Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1985.

(30) NTP. National Toxicology Program studies on pentabromoethylbenzene referenced in the ITC 15th report, pg. 100, no. 8. Submitted by V. Fung of NTP to J. Harris, Office of Toxic Substances, U.S. Environmental Protection Agency. Washington, D.C. 1985.

(31) Syracuse Research Corporation. Merrill Lane, Syracuse, NY 13210. Draft Final Technical Support Document: Pentabromoethylbenzene. Prepared for Test Rules Development Branch, Office of Toxic Substances, Environmental Protection Agency. Washington, D.C. 20460. Contract No. 68-02-4209. May 28, 1985.

(32) Lyman, W. J. Reehl, W. F. and Rosenblatt, D. H. Handbook of Chemical Property Estimation Methods. New York: McGraw-Hill. Chapters 1, 2, 4, 12, 14, and 15. 1982.

(33) Veith, G. D., DeFoe, D. L., and Bergstedt, B.J. "Measuring and estimating the bioconcentration factor of chemicals in fish." *J. Fish Res. Board Can.* 36:1040-1048. 1979.

(34) Zitko, V. and Carson, W. G. "Uptake and excretion of chlorinated diphenyl ethers and brominated toluenes by fish." *Chemosphere* 6:293-301. 1977.

(35) Bourquin, A. W., Hood, M. A., and Garnas, R. L. "An artifical microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment." Ch. 11 in Vol. 18 of Developments in Industrial Microbiology. Published by the Society for Industrial Microbiology, 1977.

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Rm. E-107, 401 M St., SW., Washington, D.C., from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Agency will supplement this record periodically with additional relevant information received.

X. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e. it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OBM to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) They are not expected to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB number 2070–0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Parts 796 and 799

Testing, Environmental protection, Recordkeeping and reporting requirements, Hazardous substances, Chemical fate, Chemicals.

Dated: November 5, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

PART 796—[AMENDED]

1. In Part 796:

a. The authority citation for Part 796 is revised to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. By adding new § 796.3341, to read as follows:

§ 796.3341 Inherent biodegradability: Modified SCAS test for chemical substances that are water insoluble or water insoluble and volatile.

(a) *Introductory Information*—(1) *Prerequisites.* (i) Water solubility.

(ii) The organic carbon content of the test material must be established.

(2) *Guidance information.* (i) Information on the relative proportions of the major components of the test material will be useful in interpreting the results obtained.

(ii) Information on the toxicity of the chemical may be useful to the interpretation of low results and in the selection of appropriate test comcentrations.

(3) *Standard documents.* This Test Guideline has been based on the paper cited under paragraph (d)(1) and (2) of this section.

(b) *Method*—(1) *Introduction, purpose, scope, relevance, application and limits of test.* (i)(A) The method is an adaptation of the Soap and Detergent Association Semi-Continuous Activated Sludge (SCAS) procedure for assessing the primary biodegradation of alkylbenzene sulphonate. The method involves exposure of the chemical to relatively high concentrations of microorganisms over a long time period (possibly several months). The viability of the microorganisms is maintained over this period by daily addition of a settled sewage feed.

(B) Since the conditions provided by the test are highly favorable to the selection and/or adaptation of microorganisms capable of degrading the test chemical, the procedure may also be used to produce microbial inocula adapted to selected chemicals for use in other tests. The test is applicable to organic chemicals that are water insoluble or water insoluble and volatile and that are not inhibitory to bacteria at the test concentration.

(ii) *Reference substances.* In some cases when investigating a new substance, reference substances may be useful; however, specific reference substances cannot yet be recommended. Data on several compounds used in ring tests are provided (see Table 1) primarily so that calibration of the method may be performed from time to time and to permit comparison of results when method is employed.

(iii) *Principle of the test method.* (A) Activated sludge from a sewage treatment plant is placed in an aeration (SCAS) unit. The test compound and settled domestic sewage are added, and the mixture is aerated for 23 hours. The aeration is then stopped, the sludge allowed to settle and the supernatant liquor is removed. The sludge remaining in the aeration chamber is then mixed with a further aliquot of test compound and sewage and the cycle is repeated.

(B) This method requires use of a compound-specific analytical technique or ^{14}C-labeled test compound. The purpose of the method is to determine the fate of the test compound in a conventional activated sludge treatment plant. To this end, a complete mass balance for the test compound is established, by quantifying parent compound in settled effluent sludge solids (insoluble test compounds whether volatile or not), effluent plus solids (insoluble test compounds whether volatile or not), and off gases (volatile test compounds only). The identification and quantification of degradation products in all phases is recommended, but not required.

(iv) *Quality Criteria*—(A) *Reproductibility.* The reproductibility of this method has not yet been established. When primary biodegradation is considered, very precise data are obtained for materials that are extensively degraded. The results reported in the reference under paragraph (d)(1) of this section suggest 95-percent confidence limits of less than ±3 percent, and this includes interlaboratory tests. As would be expected, wider confidence limits are obtained for less biodegradable chemical substances.

(B) *Possibility of standardization.* Since the method uses a feed of settled sewage, absolute standardization is not possible unless this feed were replaced by synthetic sewage. However, since the method is designed to give an indication of the biodegradability potential of a chemical and is nto a simulation test such standardization is unnecessary.

(C) *Possibility of automation.* Automation of this method would be possible but would be expensive. As the method is not labor intensive, the exercise would offer few advantages.

(2) *Description of the test procedure*—(i) *Preparations.* (A) The aeration units

are cleaned and fixed in a suitable support. The air inlet tubes are connected to the supply manifold. A small laboratory-scale air compressor is used to aerate the units, and the air is presaturated with water to reduce evaporation losses from the units.

(B) If the test compound is volatile, exhaust gases from the aeration units should be passed through a suitable trap (such as Amberlite XAD–4, Rohm and Haas, Phila., PA) to remove volatilized organics.

(C) A sample of mixed liquor from an activated sludge plant treating predominantly domestic sewage is obtained. Approximately 150 ml of the mixed liquor are required for each aeration unit.

(D) The organic carbon analyzer is calibrated using potassium hydrogen phthalate.

(E) Stock solutions of the test compounds are prepared: the concentration normally required is 400 mg/L as organic carbon which gives a test compound concentration of 20 mg/L carbon at the start of each aeration cycle if no biodegradation is occurring.

(F) If the test compound is insoluble in water at 400 mg/L it may be necessary to use ultrasound dispersion to obtain a uniform stable suspension. Alternatively, test compound may be added directly to the aeration units.

(G) The organic carbon content of the stock solutions is measured.

(ii) *Test conditions.* A high concentration of aerobic microorganisms is used, and the effective detention period is 36 hours. The carbonaceous material in the sewage feed is oxidized extensively within 8 hours of the start of each aeration cycle. Thereafter, the sludge respires endogenously for the remainder of the aeration period, during which time the only available substrate is the test compound unless this is also readily metabolized. These features, combined with daily reinoculation of the test when domestic sewage is used as the medium, provide highly favorable conditions for both adaption and biodegradation.

(iii) *Performance of the test.* (A) A sample of mixed liquor from a suitable activated sludge plant is obtained and aerated during transportation to the laboratory. Each aeration unit is filled with 150 ml of mixed liquor and the aeration is started. After 23 hours, aeration is stopped, and the sludge is allowed to settle for 45 minutes. The tap is opened and 100 ml of the supernatant liquor withdrawn. A sample of settled domestic sewage is obtained immediately before use, and 100 ml are added to the sludge remaining in each aeration unit. Aeration is started anew. At this stage no test materials are added, and the units are fed daily with domestic sewage only until a clear supernatant liquor is obtained on settling. This usually takes up to two weeks, by which time the dissolved organic carbon in the supernatant liquor at the end of each aeration cycle should be less than 12 mg/L.

(B) At the end of this period the individual settled sludges are mixed, and 50 ml of the resulting composite sludge are added to each unit.

(C) One hundred ml of settled sewage are added to the control units and 95 ml of settled sludge plus 5 ml of the appropriate test compound stock solution or suspension (400 mg/l) to the test units. If test compound is added directly to aeration units, 100 ml of settled sewage is added, as in the control units.

(D) The sludge is then allowed to settle for 45 minutes and the supernatant drained off and analyzed for parent compound. Before analysis the liquors are filtered through washed 0.45 micrometer membrane filters and certifuged. Temperature of the sample must not exceed 40 °C while it is in the centrifuge.

(E) If the test compound is insoluble or expected to sorb significantly to sludge solids, settled sludge is also collected by an appropriate means (such as centrifugation) and extracted to remove test compound, and the extract is analyzed for parent compound.

(F) If the test compound is volatile, traps for removing volatile organics from exhaust gases are also extracted and the extracts analyzed for parent compound.

(G) The fill and draw procedure under paragraph (b)(2)(iii) of this section is repeated daily throughout the test.

(H) Before settling, it may be necessary to clean the walls of the units to prevent the accumulation of solids above the level of the liquid. A separate scraper or brush is used for each unit to prevent cross contamination.

(I) The length of the test for compounds showing little or no biodegradation is indeterminate, but experience suggests that this should be at least 12 weeks.

(c) *Data and reporting*—(1) *Treatment of the results.* (i) The concentration of parent compound in settled effluent sludge solids (insoluble test compounds whether volatile or not), effluent plus solids (insoluble test compounds whether volatile or not), and off-gases (volatile test compounds only) is plotted versus time, for both test and control units. As biodegradation is achieved the level found in the test will approach that found in the control. Once the difference between the two levels is found to be constant over three consecutive measurements, three further measurements are made.

(ii) An example of the application of specific analytical technique to the SCAS test is discussed in paragraph (d)(2) of this section.

(d) *Literature references.* For additional background information on this test guideline the following references should be consulted:

(1) "A Procedure and Standards for the Determination of the Biodegradability of Alkyl Benzene Sulphonate and Linear Alkylate Sulphonate", *Journal of the American Chemical Society*, 42:986. 1965.

(2) Games, L.M., King, J.E., and Larson, R.J. "Fate and distribution of a quaternary ammonium surfactant octadecyltrimethylammonium chloride (OTAC), in wastewater treatment." *Environmental Science and Technology*, 16:483–488. 1982.

TABLE 1.—EXAMPLES OF RESULTS OF SCAS TEST ON VARIOUS COMPOUNDS USED IN THE OECD/EEC RING TEST

Test compound	O_T (mg/l)	$O_1 - O_2$ (mg/l)	Percentage biodegradation/ bioelimination
4/Acetylamino-benzene sulphonate	17.2	2.0	85
Tetrapropylene-benzene sulphonate	17.3	8.4	51.4
4-Nitrophenol	16.9	0.8	95.3
Diethylene glycol	16.5	0.2	98.8
Aniline	16.9	1.7	95.9

Duration of test 40 days.

RESULTS FOUND FOR CYCLOPENTANE TETRACARBOXYLATE

O_T (mg/l)	$O_1 - O_2$ (mg/l)	Percentage biodegradation/ bioelimination
17.9	3.2	81.1

Duration of test 120 days.

PART 799—[AMENDED]

2. In Part 799:

a. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. By adding new § 799.3205 to read as follows:

§ 799.3205 Pentabromoethylbenzene.

(a) *Identification of test substance.* (1) Pentabromoethylbenzene (CAS No. 85–22–3) shall be tested in accordance with this section.

(2) Pentabromoethylbenzene of at least 95 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture or process pentabromoethylbenzene other than as an impurity after the effective date of this section, December 27, 1985, to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests in accordance with Part 792 of this chapter, and submit data as specified in this section, Subpart A of this Part, and Part 790 of this chapter for single-phase rulemaking.

(c) *Chemical fate testing*—(1) *Water solubility*—(i) *Required testing.* A water solubility test shall be conducted with pentabromoethylbenzene in accordance with the test guideline for water solubility specified in § 796.1860 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The water solubility test shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 90 days after the effective date of the final rule.

(2) *Biodegradability and physical removal by adsorption in sludge systems*—(i) *Required testing.* Biodegradability and physical removal by adsorption tests in sludge systems shall be conducted with pentabromothylbenzene in accordance with the guideline specified in § 796.3341 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The biodegradability and physical removal by adsorption tests in sludge systems shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 90 days after the effective date of the final rule.

(3) *Biodegradability in soil*—(i) *Required testing.* Biodegradability tests in soil shall be conducted with pentabromoethylbenzene in accordance with the test guideline specified in § 796.3400 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The biodegradability test in soils shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 90 days after the effective date of the final rule.

(4) *Biodegradation rate*—(i) *Required testing.* (A) Biodegradation rate tests shall be conducted with pentabromoethylbenzene in accordance with the test guideline described in a study by A. W. Bourquin et al. entitled "An artificial microbial ecosystem for determining effects and fate of toxicants in a salt-marsh environment" published in Development in Industrial Microbiology, Volume 18, Chapter 11, 1977, published and sold by the Society for Industrial Microbiology, POB 12538, Arlington, VA 22209–8534, if any PEB is found in the aqueous phase in the semicontinuous activated sludge and physical removal by adsorption tests conducted in accordance with paragraph (c) (2) of this section. This test guidelines document is also available for inspection at both the Office of the Federal Register Information Center and the OPTS Reading Room (docket no. OPTS–42075). This incorporation by reference was approved by the Director of the Federal Register. These materials are incorporated as they exist on the effective date of this rule; a notice of any change will be published in the Federal Register.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) If required, the biodegradation rate tests shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 120 days after submission of study plans.

(d) *Environmental effects testing*—(1) *Aquatic invertebrate acute toxicity*—(i) *Required testing.* (A) An aquatic invertebrate acute toxicity test shall be conducted with pentabromoethylbenzene using the oyster, *Crassostrea virginica,* in accordance with the test guideline specified in § 797.1800 of this chapter and using modifications of the oyster acute toxicity test for PEB specified in paragraph (d)(1)(i)(B) of this section, if any PEB is found in the aqueous phase in the semicontinuous activated sludge and physical removal by adsorption tests conducted in accordance with paragraph (c)(2) of this section.

(B) *Modifications of the oyster acute toxicity test.* The following modifications for testing PEB are required.

(*1*) At least five test concentrations shall be used. The highest concentration shall be less than or equal to the solubility limit of PEB as determined under the testing specified in paragraph (c)(1)(i) of this section.

(*2*) *Concentration of dissolved test chemical.* The requirement under § 797.1800 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(*3*) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) If required, the oyster acute toxicity test shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 120 days after submission of study plans.

(2) *Bioconcentration*—(i) *Required testing.* (A) A bioconcentration test shall be conducted with pentabromoethylbenzene using the oyster, *Crassostrea virginica,* in accordance with the test guideline specified under § 797.1830 of this chapter and using modifications of the oyster bioconcentration test for PEB specified in paragraph (d)(2)(i)(B) of this section if any PEB is found in the aqueous phase in the semicontinuous activated sludge and physical removal by adsorption tests conducted in accordance with paragraph (c)(2) of this section.

(B) *Modifications.* The following modifications for testing PEB are required.

(*1*) The test concentrations shall be less than the solubility limit of PEB as determined under the testing specified in paragraph (c)(1)(i) of this section.

(*2*) At least two concentrations shall be tested which are at least a factor of 10 apart.

(*3*) *Concentration of dissolved test chemical.* The requirement under § 797.1830 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(*4*) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) If required, the bioconcentration test shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted beginning 120 days after submission of study plans. [Information collection requirements have been approved by the Office of Management and Budget under control number 2070–0033.)

[FR Doc. 85–26937 Filed 11–12–85; 8:45 am]
BILLING CODE 6560–50–M

DEPARTMENT OF DEFENSE

48 CFR Part 235

Department of Defense Federal Acquisition Regulation Supplement; Cost Sharing Policy

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule and request for comments.

SUMMARY: The Defense Acquisition Regulatory Council is considering a change to the coverage in the DoD FAR Supplement regarding cost sharing in DoD contracts. The purpose of the proposed change is to clarify existing coverage with respect to cost sharing policy.

DATE: Comments on the proposed revisions should be submitted in writing to the Executive Secretary, DAR Council, at the address shown below on or before January 13, 1986, to be considered in the formulation of the final rule. Please cite DAR Case 85–34 in all correspondence related to this issue.

ADDRESS: Interested parties should submit written comments to: Defense Acquisition Regulatory Council, ATTN: Mr. Charles W. Lloyd, Executive Secretary, DASD(P-DARS), c/o OUSDRE(M&RS), Room 3D139, Pentagon, Washington, DC 20301–3062.

FOR FURTHER INFORMATION CONTACT: Mr. Charles W. Lloyd, Executive Secretary, DAR Council, telephone (202) 697–7268.

SUPPLEMENTARY INFORMATION:

A. Background

The Defense Acquisition Regulatory Council is considering a change to the DoD FAR Supplement (DFARS) regarding cost sharing in DoD contracts. Representatives of several educational institutions have expressed concern that cost sharing places an unduly expensive burden on both educational institutions and the Government. To accommodate this concern, it is proposed to change section 235.003 of the DFARS to make clear that cost sharing is permitted when appropriate. The proposed change continues to permit cost sharing in DoD contracts but deletes material encouraging cost sharing.

B. Regulatory Flexibility Act

It is expected that the proposed change to DFARS 235.003 will have a positive effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), but the significance of that impact cannot be determined.

C. Paperwork Reduction Act Information

The proposed rule does not contain information collection requirements which require the approval of OMB under 44 U.S.C. 3501 et seq.

List of Subjects in 48 CFR Part 235

Government procurement.

Charles W. Lloyd,

Executive Secretary, Defense Acquisition Regulatory Council.

Therefore, it is proposed that 48 CFR Part 235 be amended as follows:

PART 235—RESEARCH AND DEVELOPMENT CONTRACTING

1. The authority citation for 48 CFR Part 235 continues to read as follows:

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, and DoD FAR Supplement 201.301.

2. Section 235.003 is amended by revising paragraphs (b) introductory text, (b)(70), (b)(71), and (b)(72) to read as follows:

235.003 Policy.

* * * * *

(b) *Cost Sharing.* This section provides guidelines for the use of cost sharing type contracts, as defined in FAR 16.303, for research and development type contracts (see FAR 35.003(b)).

(70) *Scope.* (i) These guidelines are applicable to research contracts.

(ii) These guidelines may be applied to development projects (i.e., projects for which the principal purpose is the production of, or design, testing or improvement of, products, materials, devices, systems or methods).

(71) *Cost Participation by Contractors.* Contractor contribution to the cost of performing research should be considered unless it is concluded that cost sharing would not be appropriate for one of the following reasons:

(i) The particular research objective or scope of effort for the contract is specified by the Government rather than proposed by the contractor; this would usually include any formal Government request for proposals for a specific project;

(ii) The research effort has only minor relevance to the commercial activities of the contractor, and the organization is proposing to undertake the research primarily as a service to the Government; or

(iii) The contractor has few or no private sources of funds from which to make a cost contribution. Cost sharing should generally not be requested if cost sharing would mean that the Government would have to provide funds through some other means (such as fees) to enable the contractor to cost share. Those contractors predominantly engaged in research and development and having little or no production or other service activities may not be in a favorable position to make a cost contribution.

(72) *Amount of Cost Sharing.* When cost sharing, the amount of cost participation by the contractor may vary in accordance with a number of factors related to the contractor's organization (profit or nonprofit) and the character of the research effort such as the following:

(i) The amount of cost participation by contractors can be any amount and should depend to a large extent on whether the research effort or results are likely to enhance the contractor's capability, expertise, or competitive position and the value of such enhancement to the contractor (but see paragraph (v) below).

(ii) If the contractor will not acquire title or the right to use inventions, patents, or technical information resulting from the research project, less contractor cost sharing is appropriate than in cases in which the contractor acquires such rights.

(iii) Less contractor cost sharing is appropriate when an area of research requires special stimulus in the national interest.

(iv) The amount of contractor cost sharing may be reduced to reflect the fact that the organization is foregoing a normal fee or profit on the research.

(v) In most cases, cost sharing with educational institutions and nonprofit organizations would not be appropriate. However, when cost participation by educational institutions, not-for-profit or nonprofit organizations is determined appropriate, the amount of sharing should normally be at least 1% of total contract cost. In most cases cost sharing of less than 5% of total project cost

would be appropriate in view of the contractor's nonprofit status and limited ability to recover the cost of such participation from non-Government sources. However, in some cases, it may be appropriate for educational institutions to provide a greater proportion of cost sharing, such as when the cost of the research consists primarily of the academic year salary of faculty members or when the equipment acquired by the institution for the project will be of significant value to the institution in its educational activities.

* * * * *

[FR Doc. 85-26924 Filed 11-12-85; 8:45 am]
BILLING CODE 3810-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for Scutellaria Montana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes to list *Scutellaria montana* (large-flowered skullcap) as an endangered species under authority of the Endangered Species Act of 1973 (Act), as amended. *Scutellaria montana* is known from only ten locations in Georgia and Tennessee, and is endangered by timber harvesting and residential development of its habitat. This proposal, if made final, would implement the Federal protection provided by the Act of *Scutellaria montana*. The Service seeks data and comments from the public on this proposal.

DATES: Comments from all interested parties must be received by January 13, 1986. Public hearing requests must be received by December 30, 1985.

ADDRESSES: Comments and materials concerning this proposal should be sent to Mr. Warren T. Parker, Field Supervisor, Endangered Species Field Station, U.S. Fish and Wildlife Service, 100 Otis Street, Room 224, Asheville, North Carolina 28801. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. Robert R. Currie at the above address (704/259-0321 or FTS 672-0321).

SUPPLEMENTARY INFORMATION:

Background

Scutellaria montana was described as a new species by Dr. A.W. Chapman (1878) from material he collected from the "mountains of Georgia." This extremely rare herbaceous member of the mint family is 30 to 55 centimeters (cm) (12 to 22 inches) tall and has opposite leaves that are 5 to 8 cm (2 to 3 inches) long and 3 to 5 cm (1 to 2 inches) wide. The attractive blue and white flowers appear in May and early June. The fruit, a light brown nutlet, matures in late June or early July (Collins, 1976; Epling, 1942). *Scutellaria montana* occurs only at the southern end of the Ridge and Valley Physiographic Province in Georgia and Tennessee. It is found on dry to slightly moist rocky slopes under a canopy of mature hardwoods (primarily oaks and hickories). All known sites show little or no evidence of disturbance due to grazing by livestock or logging. Increment boring of trees on these sites demonstrates that the trees are from 70 to over 200 years old, depending upon the site (Collins, in preparation).

During the late 19th century, Dr. Chapman frequently collected plants from the Rome, Georgia, area and *Scutellaria montana* was collected by him on several occasions. Only four additional collections of *Sutellaria montana* were made between Chapman's 19th century collections and 1973. All of these historic collections (one in Catoosa County, Georgia, and three in Hamilton County, Tennessee) have vague location descriptions and are either not locatable are destroyed. As part of a taxonomic revision of the Annulatae section of *Scutellaria*, J. L. Collins, Tennessee Valley authority (personal communication, 1985) searched most of the available suitable habitat in the vicinity of the historic locations in Georgia and Tennessee. Between 1973 and 1982, Collins discovered eight populations of *Scutellaria montana*. At least one and maybe two of these sites may have been known to Dr. Chapman, while the remainder are clearly new populations. The Tennessee Heritage Program conducted an intensive evaluation of natural areas within the Tennessee River Gorge in the vicinity of Chattanooga during 1983 and 1984. Two additional populations of *Scutellaria montana* were discovered during this intensive study. Historically, *Scutellaria montana* was probably a more widespread species. However, the mature, undistrubed hardwood stands that this species requires are quite limited. Collins (in preparation) states that "such habitats in the heavily farmed, timbered, and populated Ridge and Valley Province are quite literally few and far between."

At the present time there are ten known populations of *Scutellaria montana;* seven of these ocur in Georgia and three are in Tennessee. There are four known populations in Floyd County, Georgia. These will be designated here as sites 1 through 4 for purposes of discussion. Site 1 contains approximately 1,300 plants. Although most of the site is owned and protected by the Nature Conservancy, two small portions, containing about 200 plants, are on adjacent unprotected lands. Site 2 is privately owned and contains about 250 plants. This site is unprotected and is threatened by an adjacent quarrying operation. Sites 3 and 4 are both on privately owned unprotected lands. These sites contain only 50 and 35 plants, respectively. Gordon County, Georgia, contains one population of this species. This population is on unprotected privately owned land and contains 20 individuals. Walker County, Georgia, has two populations of *Scutellaria montana;* both are on unprotected private land and contain 60 plants and 5 plants, respectively. There are three known populations of *Scutellaria Montana*in Tennessee. Two populations are in Hamilton County, Tennessee. Both sites are on unprotected privately owned land. One site contains 45 plants and the other has only 4 plants. The last site is in Marion County, Tennessee. This location contains the largest population of *Scutellaria montana* (approximately 5,000 plants). About 50 percent of the area is on land owned and managed by the Tennessee Department of Conservation's Division of Forestry. The remainder of the site is privately owned and is on land that has been subdivided for residential development and is currently being offered for sale. At the present time, less than 7,000 *Scutellaria montana* plants are known to exist. Over 90 percent of these occur at only two sites. Although these two largest populations receive some protection, neither these nor any other known site is completely protected (Collins, in preparation; P. Somers, Tennessee Natural Heritage Program, personal communication, 1985).

Federal Government actions on this species began with section 12 of the Endangered Species Act of 1973, which directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct. This report, designated as House Document No. 94-51, was presented to Congress on

January 9, 1975. The Service published a notice in the July 1, 1975, **Federal Register** (40 FR 27823) of its acceptance of the report of the Smithsonian Institution as a petition within the context of section 4(c)(2) (now Section 4(b)(3)) of the Act, and of its intention thereby to review the status of the plant taxa named within. *Scutellaria montana* was included in the July 1, 1975, notice of review. On December 15, 1980, the Service published a revised notice of review for native plants in the **Federal Register** (45 FR 82479); *Scutellaria montana* was included in that notice as a category-1 species. On November 28, 1983, the Service published a supplement to the notice of review for native plants in the **Federal Register** (48 FR 53640). *Scutellaria montana* was changed to a category-2 species in this supplement. Category-2 species are those for which listing as endangered or threatened species may be warranted, but for which the substantial data on biological vulnerability and threats are not currently known or on file to support proposed rules. Subsequent to this notice the Service received a draft report on the status of *Scutellaria montana* (Collins, in preparation). This status report and other available information indicate tht the addition of *Scutellaria montana* to the Federal List of Endangered and Threatened Plants is warranted.

Section 4(b)(3)(B) of the Endangered Species Act, as amended in 1982, requires the Secretary to make certain findings on pending petitions within 12 months of their receipt. Section 2(b)(1) of the 1982 Amendments further requires that all petitions pending on October 13, 1982, be treated as having been newly submitted on that date. This was the case for *Scutellaria montana* because of the acceptance of the 1975 Smithsonian report as a petition. On October 13, 1983, and again on October 12, 1984, the Service found that the petitioned listing of *Scutellaria montana* was warranted but precluded by other listing actions of a higher priority and that additional data on vulnerability and threats were still being gathered. Publication of this proposal constitutes the next one-year finding that is required.

Summary of Factors Affecting the Species

Section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR Part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Scutellaria montana* Chapm. (large-flowered skullcap) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* Only parts of two of the ten known populations of *Scutellaria montana* are afforded some protection from human-induced habitat alterations. The most significant potential threats are logging, wildfires, livestock grazing, and residential development (Kral, 1983; Collins, in preparation). Approximately 50 percent of the site with the largest known population has been subdivided and is currently being offered for sale (P. Somers, personal communication, 1985). Most of the second-largest population is on land owned and managed by The Nature Conservacy and is therefore afforded protection. However, a small part of this population is on adjacent private land and is therefore susceptible to loss in the future through timber harvesting or development. The third largest population occurs on privately owned land and is currently afforded no protection from future timber harvesting or land use changes. All remaining populations are extremely small, consisting of from 4 to 60 pants, and are vulnerable to even slight modifications of their remaining habitat.

B. *Overutilization for commercial, recreational, scientific, or eductional purposes. Scutellaria montana* is not currently a significant component of the commercial trade in native plants; however, the species has potential for horticultural use and publicity of the species could generate an increased demand.

C. *Disease or predation.* Not applicable to this species at this time.

D. *The inadequacy of existing regulatory mechanisms.* In Georgia, *Scutellaria montana* is listed as a threatened species on the State list. Under the Georgia Wildflower Preservation Act of 1973, listed species are protected from unauthorized removal or cutting from public lands. Listed species offered for sale in Georgia must have a certificate stating that they did not originate from public lands. *Scutellaria montana* is listed as an endangered species on Tennessee's unofficial list of endangered, threatened and rare plant species. The recently enacted Tennessee Rare Plant Protection and Conservation Act of 1985 will provide some protection for *Scutellaria montana* once the provisions of this act are implemented later this year. None of these regulatory mechanisms offer adequate protection against the habitat disturbances that are the main threats to *Scutellaria montana.*

E. *Other natural or manmade factors affecting its continued existence. Scutellaria montana* is an extremely rare species which only occurs within a limited geographical area in southeastern Tennessee and adjacent northwestern Georgia. In some populations, loss of even a few individuals through natural fluctuations in numbers or human-induced habitat alterations could eliminate the population and thereby appreciably reduce the likelihood that the species will continue to exist.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the preferred action is to list *Scutellaria montana* as endangered. Critical habitat is not being designated for the reasons discussed below.

Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that to the maximum extent prudent and determinable, the Secretary designate any habitat of a species which is considered to be critical habitat at the time the species is determined to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for *Scutellaria montana* at this time. The species has potential for horticultural use. Increased publicity and the provision of specific location information associated with critical habitat designation could result in taking pressures on the species. Publication of critical habitat descriptions would make *Scutellaria montana* more vulnerable to taking, since most of the known populations are on privately owned land. Most of the populations consist of only a small number of individuals, and the loss of even a few could jeopardize the species. The landowners involved in managing the habitat of the large-flowered skullcap have been informed of the locations of this species and of the importance of protecting it. Therefore, no additional benefits from the notification function of critical habitat designation would result.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions

against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against taking are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402, and are now under revision (see proposal at 48 FR 29990; June 29, 1983). Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in the destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service. All known populations of *Scutellaria montana* are on privately or State owned lands. There are no known current or planned Federal activities which may affect any of these populations.

The Act and its implementing regulations found at 50 CFR 17.61, 17.62, and 17.63 set forth a series of general trade prohibitions and exceptions that apply to all endangered plant species. With respect to *Scutellaria montana*, all trade prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61, would apply. These prohibitions, in part, would make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, or sell or offer for sale this species in interstate or foreign commerce. Certain exceptions can apply to agents of the Service and State conservation agencies. The Act and 50 CFR 17.62 and 17.63 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered species under certain circumstances. It is anticipated that few trade permits would ever be sought or issued since *Scutellaria montana* is not common in cultivation or in the wild.

Section 9(a)(2)(B) of the Act, as amended in 1982, prohibits the removal and reduction to possession of endangered plant species from areas under Federal jurisdiction. Permits for exceptions to this prohibition are available through section 10(a) of the Act, until revised regulations are promulgated to incorporate the 1982 Amendments. Proposed regulations implementing this prohibition were published on July 8, 1983 (48 FR 31417), and it is anticipated that these will be made final following public comment. It is anticipated that no permits will be requested for taking the large-flowered skullcap since it is not known to occur on any Federal lands. Requests for copies of the regulations on plants and inquiries regarding them may be addressed to the Federal Wildlife Permit Office, 6th Floor Broyhill, U.S. Fish and Wildlife Service, Washington, D.C. 20204 (703/235–1903).

Public Comments Solicited

The Service intends that any final rule adopted will be accurate and as effective as possible in the conservation of endangered or threatened species. Therefore, any comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning any aspect of this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to *Scutellaria montana;*

(2) The location of any additional populations of *Scutellaria montana* and the reasons why any habitat should or should not be determined to be critical habitat as provided by Section 4 of the Act;

(3) Additional information concerning the range and distribution of this species; and

(4) Current or planned activities in the subject area and their possible impacts on *Scutellaria montana.*

Final promulgation of the regulation on *Scutellaria montana* will take into consideration the comments and any additional information received by the Service, and such communications may lead to adoption of a final regulation that differs from this proposal.

The Endangered Species Act provides for a public hearing on this proposal, if requested. Requests must be filed within 45 days of the date of the proposal. Such requests must be made in writing and addressed to the Field Supervisor, Asheville Endangered Species Field Station (see the "ADDRESSES" section).

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined by the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

References

Chapman, A.W. 1878. An enumeration of some plants—chiefly from the semitropical regions of Florida—which are either new, or which have not hitherto been recorded as belonging to the flora of the Southern States. Bot. Gaz. 3:2–6, 9–12, 17–21.

Collins, J.L. 1976. A revision of the annulate *Scutellaria* (Labiatae). PhD dissertation. Vanderbilt Univ., Nashville, Tennessee. 294 pp.

Collins, J.L. In preparation. The Taxonomy, Distribution, and Rarity of *Scutellaria montana* Chapm. (Lamiaceae).

Epling, C. 1942. The American species of *Scutellaria*. Univ. Calif. Publ. Bot. 20(1):1–146.

Kral, R. 1983. A Report on Some Rare, Threatened, or Endangered Forest-related Vascular Plants of the South. Tech. Publ. R8–TP–2. USDA—Forest Service. Pp. 1010–1013.

McCollum, J.L., and D.R. Ettman. 1977. Georgia's Protected Plants. Georgia Department of Natural Resources, Atlanta, Georgia. 66 pp.

Author

The primary author of this proposed rule is Mr. Robert R. Currie, Endangered Species Field Station, U.S. Fish and Wildlife Service, 100 Otis Street, Room 224, Asheville, North Carolina 28801 (704/259–0321 or FTS 672–0321).

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Proposed Regulation Promulgation

PART 17—[AMENDED]

Accordingly, it is hereby proposed to amend Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, as set forth below:

1. The authority citation for Part 17 continues to read as follows:

Authority: Pub. L. 93–205, 87 Stat. 884; Pub. L. 94–359, 90 Stat. 911; Pub. L. 95–632, 92 Stat. 3751; Pub. L. 96–159, 93 Stat. 1225; Pub. L. 97–304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*).

2. It is proposed to amend § 17.12(h) by adding the following, in alphabetical order under the family Lamiaceae, to the List of Endangered and Threatened Plants:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
Lamiaceae—Mint family:						
* * * * *						
Scutellaria montana	large-flowered skullcap	U.S.A. (GA, TN)	E		NA	NA
* * * * *						

Dated: October 8, 1985.

P. Daniel Smith,

Acting Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 85–26960 Filed 11–12–85; 8:45 am]

BILLING CODE 4310–55–M

Notices

Federal Register
Vol. 50, No. 219
Wednesday, November 13, 1985

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

International Trade Administration

[C-307-501]

Termination of Countervailing Duty Investigation: Certain Circular Welded Carbon Steel Standard Pipe From Venezuela; and Preliminary Affirmative Countervailing Duty Determination: Certain Circular Welded Carbon Steel Line Pipe From Venezuela

AGENCY: Import Administration, International Trade Administation, Commerce.

ACTION: Notice.

SUMMARY: In a letter dated October 21, 1985, petitioners, the standard pipe subcommittee of the Committee on Pipe and Tube Imports (CPTI) and the individual members of that subcommittee, withdrew their countervailing duty petition filed on February 28, 1985, with respect to certain circular welded carbon steel standard pipes and tubes (standard pipe) from Venezuela. Based on this withdrawal by the petitioners, we are terminating our investigation with respect to standard pipe, as described in the "Scope of Investigations" section of this notice.

With respect to certain circular welded carbon steel line pipe (line pipe), we preliminarily determine that certain benefits which constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers or exporters in Venezuela of line pipe, as described in the "Scope of Investigations" section of this notice. The estimated net subsidy for line pipe is 76.00 percent *ad valorem*.

We have notified the U.S. International Trade Commission (ITC) of our determination. We are directing the U.S. Customs Service to suspend liquidation of all entries of line pipe from Venezuela that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice, and to require a cash deposit or bond on entries of this product in the amount equal to the estimated net subsidy.

If this investigation proceeds normally, we will make our final determination by January 20, 1986.

EFFECTIVE DATE: November 13, 1985.

FOR FURTHER INFORMATION CONTACT: Barbara Tillman, Tom Bombelles or Ellie Shea, of the Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230; telephone: (202) 377-2438, (202) 377-3174 or (202) 377-1784.

SUPPLEMENTARY INFORMATION:

Preliminary Determination

Based upon our investigation, we preliminarily determine that there is reason to believe or suspect that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers or exporters in Venezuela of line pipe. For purposes of this investigation, the following programs are found to confer subsidies:

- Loans Through the Industrial Credit Fund
- Multiple Exchange Rates
- Export Certificates for Credit Against Income Taxes
- Preferential Export Financing
- Subsidies to Upstream Suppliers of Steel Inputs

—Government Equity Infusion
—Preferential Government Credit
—Sales Tax Exemption

We preliminarily determine the estimated net subsidy for certain circular welded carbon steel line pipe to be 76.00 percent *ad valorem*.

Case History

On February 28, 1985, we received a petition filed with respect to certain circular welded carbon steel pipes and tubes. By amendment dated March 12, 1985, counsel for petitioners clarified that the petition was being filed on behalf of the standard pipe subcommittee and the line pipe subcommittee of the Committee on Pipe and Tube Imports (CPTI) and by individual manufacturers of standard and line pipe. With respect to line pipe, the individual manufacturers supporting the petition were Sawhill Tubulars Division of Cyclops Corp., Tex-Tube Division of Cyclops Corp., Laclede Steel Company, and Wheatland Tube Corp.

In compliance with the filing requirements of § 355.26 of our regulations (19 CFR 355.26), the petition alleges that manufacturers, producers or exporters in Venezuela of standard pipe and line pipe, directly or indirectly, receive benefits which constitute subsidies within the meaning of section 701 of the Act, and that these imports materially injure, or threaten material injury to, U.S. industries.

We found that the petition contained sufficient grounds upon which to initiate countervailing duty investigations, and on March 20, 1985, we initiated these investigations (50 FR 12063). We stated that we expected to issue preliminary determinations by May 24, 1985.

Since Venezuela is a "country under the Agreement" within the meaning of section 701(b)(3) of the Act, an injury determination is required for these investigations. Therefore, we notified the ITC of our initiations. On April 15, 1985, the ITC determined that there is a reasonable indication that imports of certain circular welded carbon steel pipes and tubes materially injure, or threaten material injury to, U.S. industries (50 FR 16167).

We presented a questionnaire concerning the allegations to the government of Venezuela in Washington, D.C. on April 8, 1985. On May 22, 1985, we received responses to our questionnaire from the government of Venezuela and from C.A. Conduven, the only known producer and exporter in Venezuela of standard pipe and line pipe to the United States.

On March 25 and 26, 1985, we received information from petitioners which established a reasonable basis to believe or suspect that the products under investigation benefited from upstream subsidies in the form of subsidized steel inputs. On April 26, 1985, pursuant to section 703(h) of the Act, we extended the due date for the preliminary determinations to November 5, 1985 (50 FR 18899). On May 21, 1985, we presented an upstream subsidy questionnaire. However, we received no response to th upstream questionnaire from the government of Venezuela, from SIDOR, the alleged upstream supplier, or from Conduven.

On October 21, 1985, we received a letter from the standard pipe subcommittee of the CPTI and the individual member companies of that subcommittee withdrawing their countervailing duty petition with respect to standard pipe (See "Termination of Standard Pipe Investigation" section of this notice).

On October 11, 1985, we received a letter from US Steel Corporation requesting that the Department terminate the countervailing duty investigation of line pipe from Venezuela. We received the same request from Bethlehem Steel Company on October 30, 1985, and from LTV Steel Tubular Products Company on November 5, 1985. Information in the record indicates that there is a serious question as to whether a substaintial majority of the domestic industry supports the investigation of line pipe. We will be obtaining further information to determine whether it is appropriate to terminate this investigation.

On October 29, 1985, petitioners in the line pipe investigation filed a letter stating that they were amending their petition to allege in the alternative that a regional industry producing line pipe is being materially injured and that the petition is brought on behalf of line pipe producers in that region. The region is alleged to consist of Texas, Louisiana, Oklahoma, Kansas, Mississippi, Alabama and Florida. There is a serious question as to the timeliness of this amendment.

Scope of Investigations

The products covered by these investigations are:

(1) circular welded carbon steel pipes and tubes, with an outside diameter of .375 inch or more but not over 16 inches, of any wall thickness, currently classifiable in the *Tariff Schedules of the United States, Annotated* (TSUSA), under items 610.3231, 610.3234, 610.3241, 610.3242, 610.3243, 610.3252, 610.3254, 610.3256, 610.3258 and 610.4925. These products, commonly referred to in the industry as standard pipe or structural tubing, are produced to various ASTM specifications, most notably A–120, A–53 or A–135.

(2) certain circular welded carbon steel line pipe with an outside diameter of .375 inch or more but not over 16 inches, and with a wall thickness of not less than .065 inch, currently classifiable in the *Tariff Schedules of the United States, Annotated* (TSUSA), under items 610.3208 and 610.3209. These products are produced to various API specifications for line pipe, most notably API–5L or API 5LX.

Termination of Standard Pipe Investigation

On October 21, 1985, we received a letter from the standard pipe subcommittee of the CPTI and the individual member companies of that subcommittee withdrawing their countervailing duty petition with respect to standard pipe. Under section 704(a) of the Tariff Act of 1930, as amended by section 604 of the Trade and Tariff Act of 1984 (the Act), upon withdrawal of a petition, the administering authority may terminate an investigation after giving notice to all parties to the investigation and after assessing the public interest as required by the Act. We have taken into account the public interest factors set out in section 704(a)(2) of the Act and consulted with potentially affected producers, workers, and consuming industries, and with the ITC. On the basis of our assessment of the public interest factors and our consultations, we have determined that termination of our investigation of standard pipe from Venezuela would be in the public interest.

We have notified all parties to the investigation and the ITC of petitioners' withdrawal of their countervailing duty petition with respect to standard pipe and our intention to terminate. For these reasons, we are terminating our investigation with respect to standard pipe. Our investigation of line pipe will continue according to statutory procedures.

Analysis of Programs

Throughout this notice, we refer to certain general principles applied to the facts of the current investigation. These principles are described in the "Subsidies Appendix" attached to the notice of "Cold-Rolled Carbon Steel Flat-Rolled Products from Argentina: Final Affirmative Countervailing duty Determination and Countervailing Duty Order", which was published in the April 26, 1984 issue of the **Federal Register** (49 FR 18006).

Consistent with our practice in preliminary determinations, when a response to an allegation denies the existence of a program, receipt of benefits under a program, or eligibility of a company or industry under a program, and the Department has no persuasive evidence showing that the response is incorrect, we accept the response for purposes of the preliminary determination. All such responses are subject to verification. If the response cannot be supported at verification, and the program is otherwise countervailable, the program will be considered a subsidy in the final determination.

For purposes of this preliminary determination, the period for which we are measuring subsidization ("the review period") is calendar year 1984.

C.A. Conduven is the only known producer and exporter in Venezuela of line pipe to the United States for which we have received information from the government of Venezuela. In addition, we have identified C.V.G. Siderurgica del Orinoco, C.A. (SIDOR) as the upsteram supplier of steel inputs to Conduven.

Because we did not receive responses to our upstream quentionnaire from the government of Venezuela, SIDOR or Conduven, we are using the best information available as required under § 355.3? of our regulations (19 CFR 355.39) on which to base our analysis of the upstream subsidy allegation. Based on our analysis of the petition and the responses to our questionnaire, we preliminarly determine the following:

I. Programs Preliminarily Determined to Confer Subsidies

We preliminarily determine that subsidies are being provided to manufacturers, producers or exporters in Venezuela of certain circular welded carbon steel line pipe under the following programs.

A. Loans Through the Industrial Credit Fund

Petitioners allege that Conduven receives large, low-cost loans directly from the government and government agencies on terms inconsistent with commercial considerations. According to Conduven's response, it received two loans from the Industrial Credit Fund (FONCREI) which were outstanding during the review period. Because the government of Venezuela has provided no information on the availability and distribution of FONCREI loans in the Venezuelan economy we preliminarily determine that these loans are limited to a specific enterprise or industry or group of enterprises or industries.

As outlined in the Subsidies Appendix, the appropriate benchmark for long-term loans will be company-specific, unless the company lacks adequate comparable commercial experience. According to Conduven's response, the company issued a bond offering in the same year as the receipt of one of the FONCREI loans. Therefore, for the first FONCREI loan, we are using the interest rate in Conduven's bond offering as the company-specific long-term benchmark. Using this rate, we find that the interest rate on the FONCREI

loan is inconsistent with commercial considerations and as such confers a benefit which constitutes a domestic subsidy.

We were unable to determine from the response whether Conduven had received any commercial loans or issued any bonds in the year that the second FONCREI loan was received. Therefore, we are using the national average rate of return on eight-to-ten year bonds issued by non-financial companies, which was provided in the government response, as our benchmark. Using this rate we find that the second FONCREI loan to Conduven is on terms inconsistent with commercial considerations and, as such, also confers a benefit which constitutes a domestic subsidy.

To calculate the benefit from these loans, we used the methodology described in the Subsidies Appendix for long-term loans. We then allocated this benefit over total sales. On this basis, we calculate an estimated net subsidy of 0.04 percent *ad valorem*.

B. Multiple Exchange Rates

On February 22, 1983, the government of Venezuela authorized the establishment of a multiple exchange rate system after more than 19 years at a fixed rate system of 4.30 bolivares (Bs.) to the dollar. In its response, the government of Venezuela stated that this change in the exchange rate was made in an attempt to gradually devalue the bolivar while avoiding the inflationary impact of a sudden devaluation.

The Central Bank of Venezuela (CBV) and the Ministry of Finance (MOF) signed an Exchange Agreement on February 28, 1983, establishing a four-tiered exchange rate system. The first exchange rate is a fixed rate of Bs. 4.30 to the dollar. This rate is applied to the sale of foreign exchange by the CBV for payments on foreign-source private and public debt, the importation of essential goods and services, and the sale of foreign exchange from the state-owned oil industries (PDVSA), iron ore industry (FERROMINERA), and the Venezuelan Investment Fund. The second rate is also a fixed rate, but at Bs. 6.00 to the dollar. This rate is applied to the sale of foreign exchange by the CBV for the importation of less essential goods, foreign exchange obtained from the export of goods and services from state-owned enterprises (other than PDVSA and FERROMINERA), and foreign exchange on exports by the private sector when offerd to the CBV.

The other two rates established are a foreign exchange free market rate (an average Bs. 13.03 to the dollar during 1984) established for all exchange operations not specifically provided for elsewhere, and a "free-but-official" rate for the purchase and sale of dollars by the CBV in the free market. According to the response from the government of Venezuela, the private sector used the free market exclusively, and did not offer its foreign exchange to the CBV, under the second rate described above.

Under this Exchange Agreement, the government also established the Office of Preferential Exchange Regime (RECADI) to administer the multiple exchange rate system. RECADI is responsible for handling applications from importers for merchandise categorized as essential or less essential. To receive the more preferential exchange rate for imports, an importer must submit an application to RECADI identifying the value, quantity and payment terms of the intended purchase. After RECADI reviews the application, it may authorize the use of the more preferential exchange rate to cover the particular purchase.

In May 1983, the government began gradually to allow the public sector companies (other than PDVSA and FERROMINERA) to use the free market rate. Until this time only private companies had access to the free market. In its response, the government stated that it excluded PDVSA and FERROMINERA from the free market during 1983 and 1984 because it recognized that their substantial earnings would have an inflationary impact on the overall economy.

On February 24, 1984, the government of Venezuela signed an Exchange Control Agreement between the MOF and the CBV which increased the exchange rate for importation of less essential goods from Bs. 6.00 to Bs. 7.50 to the dollar. In addition, this Agreement created the "quota share" policy which required all exporters to sell back to the Central Bank the dollars earned on the imported component of the finished product at the same exchange rate used for the importation. Until the 1984 Agreement was signed, exporters could buy imports at the Bs. 4.30 or the Bs. 7.50 to the dollar rate and upon exportation sell the dollars earned on the imported component at the free market exchange rate. The difference in the exchange rate between the lower rate used to purchase imports and the free market rate for selling dollars provided a benefit to exporters.

To implement the quota share policy, the government published Resolution No. 84-05-01 in May 1984. This resolution required that the value of 50 percent of the import content of the exported product, as calculated in the ICE certificates used for granting export bonds, be sold to the CBV at the lower exchange rate of Bs. 7.50 to the dollar (the same rate at which they buy foreign exchange for imports). To enforce the quota share program, the CBV requires exporters to sign a contract upon exportation stating that the specified proportion of export earnings will be sold to the CBV at the same rate used for importation of he material imputs.

Under the multiple exchange rate system, one dollar received for export sales yield more bolivares than Conduven pays to purchase one dollar for imports. Because receipt of the higher exchange rate is contingent upon selling dollars earned from export sales, we consider the multiple exchange rate to confer an export subsidy. Nevertheless, since our experience in examining multiple exchange rate systems is limited, we welcome comments on the calculations of benefits received through multiple exchange rate systems.

To calculate the benefit from this program, we subtracted the exchange rate applicable to Conduven's purchase of imports from the weighted average exchange rate received by Conduven when selling dollars from export sales. We multiplied this difference by the total 1984 export value for Conduven in dollars and allocated the product over Conduven's total 1984 export sales in bolivares. On this basis, we calculate an estimated net subsidy of 38.12 percent *ad valorem*.

C. Export Certificates for Credit Against Income Taxes

Petitioners allege that Venezuelan steel exporters receive certificates to encourage exports, which may be sold for cash or used to pay income taxes. The value of the certificate is based on a percentage of the f.o.b. value of the exported merchandise.

Accounding to the responses of the government of Venezuela and Conduven, under this program a certain percentage of the value of an export shipment is returned to the exporter. The percentage of the return depends on the proportion of domestic content of the merchandise and certain policy objectives of the government, such as maintaining a high rate of employment. Upon export, a shipper receives an export certificate specifying the amount to be returned to the exporter. This amount is determined by multiplying the exporter's allowable rebate percentage by the f.o.b. value of the export in dollars. This dollar value is then converted to bolivares at a rate of Bs. 7.5

to the dollar. The certificate, along with accompanying shipping and sales documents, must be sent to the Central Bank, which then issues the export bond. This bond may be sold for cash or used to pay taxes. Because this program is limited to exporters and does not operate to rebate any indirect taxes, we preliminarily determine that this program confers an export subsidy on the merchandise under investigation.

To calculate the benefit, we multiplied the percentage rebate for which Conduven is eligible by the f.o.b. value of Conduven's exports in dollars. We then multiplied this amount by 7.5 to determine the value of the benefit in bolivares. Allocating this benefit over total export sales, we calculate an estimated net subsidy of 13.30 percent *ad valorem*.

D. Preferential Export Financing

Petitioners allege that Venezuelan steel exporters receive preferential short-term export financing through the Export Financing Fund (FINEXPO), a program administered by the Banco Industrial de Venezuela.

According to the response of the government, FINEXPO loans are extended at a fixed annual interest rate to finance a company's exports. Conduven had several FINEXPO loans outstanding during the reveiw period. To determine whether FINEXPO financing provides a benefit which confers an export subsidy, we compared the interest rate on FINEXPO loans to the appropriate benchmark rate.

In 1984, annual interest rates published by the Central Bank of Venezuela for short-term working capital loans from commercial banks were above those charged by FINEXPO. Using these published short-term rates as our benchmark, we preliminarily determine that FINEXPO loans confer a benefit which constitutes an export subsidy. Comparing the benchmark interest rates which were in effect on the date of receipt of each FINEXPO loan to the FINEXPO rate, we calculate an estimated net subsidy of 0.40 percent *ad valorem*.

II. Subsidies to Upstream Suppliers of Steel Inputs

Petitioners allege that Conduven receives an "upstream subsidy" through the purchase of subsidized steel inputs from SIDOR.

Under section 771A(a) of the Act, we must apply the following tests in order to determine whether "upstream subsidies" are being paid or bestowed upon the products under investigation:

> The term 'upstream subsidy' means any subsidy described in section 771(5)(B) (i), (ii), or (iii) by the government of a country that
>
> (1) is paid or bestowed by that government with respect to a product (hereafter referred to as an 'input product') that is used in the manufacture or production in that country of merchandise which is the subject of a countervailing duty proceeding;
>
> (2) in the judgment of the administering authority bestows a competitive benefit on the merchandise; and
>
> (3) has a significant effect on the cost of manufacturing or producing the merchandise.

1. Domestic Subsidies

Because the government of Venezuela, Conduven and SIDOR did not respond to our questionnaire requesting information on upstream subsidies, our analysis of this issue is based on "best information available", as required under § 355.39 of our regulations (19 CFR 355.39). For our preliminary determination of the number and level of domestic subsidies received by SIDOR, we are using, as best information available, our "Preliminary Affirmative Countervailing Duty Determinations: Certain Carbon Steel Products from Venezuela" (50 FR 11227) published on March 20, 1985. Based on that determination, we preliminarily determine that domestic subsidies are being provided to SIDOR, Conduven's domestic supplier of hot-rolled carbon steel sheet (hereafter referred to as skelp) used in the manufacture of line pipe, under the following programs:

a. Preferential Government Credit
b. Sales Tax Exemptions
c. Government Equity Infusions

SIDOR was the only company producing and exporting skelp in that investigation of certain carbon steel products.

Our determination with respect to each of these domestic subsidy programs is outlined in the notice of that case. The total estimated domestic subsidy found for these three programs was 28.06 percent *ad valorem* for hot-rolled sheet. Accordingly, we determine that the first upstream subsidy test has been met.

2. Competitive Benefit

The second step of the test outlined in section 771A of the Act is the determination of whether the subsidies received by the upstream supplier bestow a "competitive benefit" on the merchandise under investigation. Under the terms of section 771(b)(1),

> [a] competitive benefit has been bestowed when the price for the input product . . . is lower than the price that the manufacturer or producer of merchandise which is the subject of a countervailing duty proceeding would otherwise pay for the product in obtaining it from another seller in an arms-length transaction.

We would compare SIDOR's prices to prices charged by unsubsidized Venezuelan producers of skelp used by line pipe producers. However, we are unaware of any unsubsidized Venezuelan producers of skelp. Therefore, as the next step, we would have compared SIDOR's prices to prices paid for unsubsidized imported steel used by Conduven, or failing that, to respondents' information on world market prices for their steel inputs. In the absence of any such information from Conduven or SIDOR, we have used the best information otherwise available to calculate a "benchmark" price.

As best information available, we reviewed the average Japanese f.o.b. price of skelp in 1984 for exports to countries other than the United States, as shown in Japanese export statistics. To this average Japanese price, we added average ocean freight and insurance charges corresponding to shipments of skelp from Japan to the east coast of the United States as recorded in U.S. government statistics.

In this way we calculated a benchmark price for skelp based on the average Japanese f.o.b. price plus freight and insurance.

Because we did not receive a response to our upstream questionnaire, we had no specific price information on skelp from SIDOR to use as a comparison with our benchmark price. Therefore, as best information available, we are assuming that SIDOR passed through 100 percent of the value of its domestic subsidies to Conduven. On this basis we preliminarily determine that the competitive benefit test has been met.

3. Significant Effect

The third and final step of the statutory test is to determine whether the subsidy received by the upstream supplier has a significant effect on the cost of manufacturing or producing the merchandise. Again, using best information available, we multiplied the *ad valorem* domestic subsidy rate calculated for SIDOR in our previous investigation by the percentage that the petitioners claim the subsidized steel inputs account for in the cost of producing line pipe. We found that the estimated net subsidy accounted for more than five percent of the cost of manufacturing or producing line pipe. For purposes of this preliminary determination, we consider that the "significant effect" test has been met.

All three tests outlined in section 771A(a) having been met, we

preliminarily determine that benefits bestowed upon SIDOR confer an upstream subsidy upon the products under investigation.

4. Measurement of Upstream Subsidization

Under section 771A(c) of the Act,

> the administering authority shall include in the amount of any countervailing duty imposed on the merchandise an amount equal to the amount of the competitive benefit . . . except that in no even shall the amount be greater than the amount of subsidization determined with respect to the upstream product.

Pursuant to this statutory language, and on the basis of best information available, we assumed that SIDOR's price to Conduven for skelp is lower than our benchmark price by the percentage amount of the estimated net domestic subsidy received by SIDOR.

To derive a figure for the tonnage of skelp purchased from SIDOR by Conduven, we multiplied the tonnage of pipe and tube produced by Conduven in 1984 by an estimated yield factor of skelp to pipe and tube.

We multiplied the net subsidy per ton received by Conduven by our estimated figure for tonnage that SIDOR sold to Conduven in 1984. We then divided this amount by the total value of pipe and tube sold by Conduven in 1984 and calculated an estimated net upstream subsidy of 24.14 percent *ad valorem*.

III. Program Preliminarily Determined Not To Confer a Subsidy

We preliminarily determine that subsidies are not being provided to manufacturers, producers or exporters in Venezuela of line pipe under the following program.

A. Import Duty Reductions

Petitioners allege that the government of Venezuela provides import duty reductions on capital equipment and raw materials to steel producers to encourage exports. Title IV of the Venezuela Organic Customs Law authorizes total or partial import duty exemptions for diverse sectors of the economy. Article 89 of this law specifically allows duty exemptions for "effects destined to industry, agriculture, stock-raising, transportation, mining, fishing, and manufacturing." Duty exemptions are granted whenever national production or supply is inadequate to meet the damand for a particular item. Since import duty reductions or exemptions are not limited to a specific enterprise or industry, or group of enterprises of industries, nor do they operate to stimulate export performance, we preliminarily determine that this program does not provide benefits which constitute subsidies.

B. Loans Through the Industrial Financing Company of Venezuela and the Banco Industrial de Venezuela

Petitioners allege that Conduven receives large, low-cost loans from the government and government agencies on terms inconsistent with commercial considerations. According to Conduven's response, it had one loan from the Industrial Financing Company of Venezuela (FIVCA) and one loan from the Banco Industrial de Venezuela (BIV), which were outstanding during the review period. In its response, the government of Venezuela did not provide any information on the distribution or availability of FIVCA or BIV loans. We also have no description of the organization or purpose of FIVCA. However, Conduven's response indicates that this is a loan "from a national financial institution". We did receive information that the BIV is a government-controlled bank which makes loans to the industrial sector of the Venezuelan economy.

We therefore preliminarily determine that the FIVCA and BIV loans are limited to a specific enterprise or industry or group of enterprises or industries. We are unable to determine whether Conduven had any comparable commercial debt experience in the year these loans were received against which to measure any benefit from these loans. Therefore, for the purposes of this preliminary determination, we are using the national average rates of return on eight-to-ten year bonds issued by non-financial companies as provided in the government response. Using these rates as our benchmark against which to measure the interest rate on the FIVCA and BIV loans, we find that the interest rates on these loans are not inconsistent with commercial considerations and therefore do not constitute subsidies.

IV. Program Preliminarily Determined Not To Be Used

We preliminarily determine that manufacturers, producers or exporters in Venezuela of line pipe did not use the following program.

A. Preferential Pricing of Inputs Used To Produce Exports

Petitioners allege that SIDOR, the state-owned integrated producer, charges a preferential price to domestic customers who purchase steel for further processing and subsequent export. It is alleged that these discounts range from 15 percent to 40 percent of the regular domestic price and are directed by the government in order to confer a benefit on steel exporters. Conduven stated in its response that it did not receive preferential pricing of inputs used to produce exports of line pipe; therefore, we preliminarily determine that this program is not used.

Suspension of Liquidation

In accordance with section 703(d) of the Act, we are directing the U.S. Customs Service to suspend liquidation of all entries of certain circular welded carbon steel line pipe from Venezuela which are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register** and to require an *ad valorem* cash deposit or bond for each such entry in the amount of 76.00 percent *ad valorem*. This suspension will remain in effect until further notice.

ITC Notification

In accordance with section 703(f) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to this investigation. We will allow the ITC access to all privileged and confidential information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Deputy Assistant Secretary for Import Administration.

The ITC will determine whether these imports materially injure, or threaten material injury to, a U.S. industry within 120 days after the Department makes its preliminary affirmative determination or 45 days after its final affirmative determination, whichever is latest.

Public Comment

In accordance with § 355.35 of our regulations, we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on this preliminary determination at 10:00 a.m. on December 10, 1985, at the U.S. Department of Commerce, Room 1413, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230. Individuals who wish to participate in the hearing must submit a request to the Deputy Assistant Secretary for Import Administration, Room B-099, at the above address within 10 days of the publication of this notice.

Requests for a hearing should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) the reason for attending; and (4) a list of the issues to be

discussed. In addition, at least 10 copies of pre-hearing briefs must be submitted to the Deputy Assistant Secretary by November 14, 1985. Oral presentations will be limited to issues raised in the briefs.

In accordance with 19 CFR 355.33(d) and 19 CFR 355.34, written views will be considered if received not less than 30 days before the final determination or, if a hearing is held, within 10 days after the hearing transcript is available.

This notice is published pursuant to section 703(f) of the Act (19 U.S.C. 1671b(f)).

Gilbert B. Kaplan,

Acting Deputy Assistant Secretary for Import Administration.

November 5, 1985.

[FR Doc. 85-26918 Filed 11-12-85; 8:45 am]

BILLING CODE 3510-DS-M

Department of the Interior; Applications for Duty-Free Entry of Scientific Instruments

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897; 15 CFR Part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with § 301.5(a) (3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, DC 20230. Application may be examined between 8:30 A.M. and 5:00 P.M. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket number: 86-015. Applicant: Department of the Interior, U.S. Geological Survey, Gulf Coast Hydroscience Center, NSTL, MI 39529. Instrument: Ring Shear Type Debris Flow Apparatus. Manufacturer: Marui and Company, Limited, Japan. Intended use: Studies of the mechanics of debris flow (or mudflow) in well-designed experiments conducted reproducing the desired states of stress and deformation at the various stages of debris flow processes, such as during occurrence, growth, equilibrium, deposition, and stoppage. The objectives of these experiments are to determine the values of various parameters describing the rheological behaviors of debris flows. The rheological parameters to be determined include, but are not limited to, the flow behavior index, consistency index, dynamic angle of internal friction, and compressibility of soil or sediment-water mixture. Application received by Commissioner of Customs: October 22, 1985.

Docket number: 86-022. Applicant: University of New Hampshire, Instrumentation Center, Parsons Hall, Durham, NH 03824. Instrument: Electron Microscope with Scanning Attachment, Model H-600 and Accessories. Manufacturer: Hitachi, Limited, Japan. Intended use: In vitro and in vivo studies of animal and plant tissues and microbial cells with subsequent observation of electron microscopy to provide better understanding basic problems in biology and health research. The instrument will also be used for training in EM techniques and preparation for EM research in the courses Animal Science 714, Microbiology 710 and Zoology 796-896. Application received by Commissioner of Customs: October 22, 1985.

Docket number: 86-023: Applicant: University of California, Los Angeles, Department of Chemistry and Biochemistry, 405 Hilgard Avenue, Los Angeles, CA 90024. Instrument: Mass Spectrometer, Model ZAB-SE with Accessories. Manufacturer: VG Analytical Limited, United Kingdom. Intended use: Investigation of the following problems: (1) Host-guest complexation phenomena in systems where complexing partners are designed and synthesized, (2) synthetic molecules of polyintercalators for DNA and proximity labels, (3) the possible role of protein carboxyl methylation in the repair of aged damaged proteins, (4) the use of Boron-10 labeled antibodies in a Neutron-Capture Therapy of cancer, (5) the total synthesis of biologically active natural products, (6) synthesis of oligonucleotide probes in the study of the molecular genetics of atherosclerosis, (7) use of transition metal ions and complexes for the elucidation of the mechanisms of biological dioxygen activation, (8) study of the pathways of arginie degradation in *Klebsiela aerogenes*, (9) polypeptide sequencing and identification of chemical modifications of polypeptides, (10) oxidative cleavage of DNA by complexes of Cu(I) with phenanthroline and its derivatives, (11) synthetic and catalytic activity of new main group carborane cages, (12) investigations into anionic and neutral trirutheneum cluster complexes, and (13) gas phase ion chemistry. The instrument will be used to analyze samples prepared by graduate students with B.S. degrees in their research that is required to obtain the Ph.D. degree. Application received by Commissioner of Customs: October 21, 1985.

Docket number: 86-026. Applicant: State University of New York at Buffalo, 3435 Main Street, Buffalo, NY 14214. Instrument: Electron Microscope, Model JEM-100CXII with Accessories (Side Entry Type). Manufacturer: JEOL, Limited, Japan. Intended use: Research in the following areas:

(1) Analysis of mechanisms of cell motility.

(2) Examination of nerve structure and pathways.

(3) Studies of gametes during fertilization.

The instrument will also be used in training graduate students in techniques of electron microscopy. Application received by Commissioner of Customs: October 22, 1985.

Docket number: 86-027. Applicant: Saint Francis Medical Center, 530 NE Glen Oak Avenue, Peoria, IL 61637. Instrument: Extracorporeal Shockwave Lithotripter. Manufacturer: Dornier System GmbH, West Germany. Intended use: The instrument is intended to be used to crush kidney stones non-invasively on patients diagnosed with kidney stone diseases. Application received by Commissioner of Customs: October 23, 1985.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85-26943 Filed 11-12-85; 8:45 am]

BILLING CODE 3510-DS-M

Environmental Protection Agency; Applications for Duty-Free Entry of Scientific Instruments

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897; 15 CFR 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with §§ 301.5(a) (3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 85-079R. Applicant: U.S. Environmental Protection Agency, 6201 Congdon Boulevard, Duluth, MN 55804. Instrument: Gas Chromatograph/

Mass Spectrometer/Data System, Model 8230. Original notice of this resubmitted application was published in the **Federal Register** of February 27, 1985.

Docket Number: 86-011. Applicant: California Institute of Technology, Pasadena, CA 91125. Instrument: VG Sector Thermal Ionization Mass Spectrometer with Accessories. Manufacturer: VG Instruments, United Kingdom. Intended Use: The instrument will be used for the isotope analysis of earth materials for the determination of formation ages, pre-formation geochemical evolution of formational materials and for age determinations of post-formational thermal and deformational events associated with mountain building. Environmental goechemical work will consist of precise concentration determinations of lead in natural waters and in biological materials at sub-nanogram levels. The instrument will also be used to demonstrate the physics of ion optics and high vacuum systems, goechemical research techniques, and a multi-faceted distributed interface data system. Also, graduate student training and thesis research will be performed on the instrument. Application received by Commissioner of Customs: October 22, 1985.

Docket Number: 86-012. Applicant: University of California at Berkeley, Purchasing Department, 2405 Bowditch Street, Berkeley, CA 94720. Instrument: X-Ray Streak Camera, Model LMSC. Manufacturer: Kentech Instruments, United Kingdom. Intended use: The instrument is intended to be used for the study of x-ray emission from metal targets in experiments designed to produce a new type of x-ray source. Application received by Commissioner of Customs: October 22, 1985.

Docket Number: 86-013. Applicant: Children's Hospital and Health Center, 8001 Frost Street, San Diego, CA 92123. Instrument: Electron Microscope, Model EM 410LS with Accessories. Manufacturer: Philips, The Netherlands. Intended use: Scientific investigation of pediatric neoplasm, renal disease, and sudden infant death syndrome. Topics currently under investigation include delineation of brain stem nuclei important in the regulation of respiration in the opossum. These studies are being done in collaboration with developmental respiratory physiology investigations, the results of which will be correlated with ultrastructural findings. Application received by Commissioner of Customs: October 22, 1985.

Docket number: 86-014. Applicant: University of California, Berkeley, Purchasing Department, 2405 Bowditch Street, Berkeley, CA 94720. Instrument: Cryotrans System for ISI-DS130 S.E.M., Model Polaron E7300. Manufacturer: Hexland Limited, United Kingdom. Intended use: The instrument will be used to freeze, dissect and observe a wide variety of plant and animal tissues in both basic science and biomedical applications. In addition, the instrument will be used for educational purposes in the courses: Botany 231/231C, Biophysics 204C and Biology 499. Application received by Commissioner of Customs: October 22, 1985.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85-26944 Filed 11-12-85; 8:45 am]

BILLING CODE 3510-DS-M

Export Trade Certificate of Review Receipt of Application

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of Application.

SUMMARY: The Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review. This notice summarizes the conduct for which certification is sought and requests comments relevant to whether the certificate should be issued.

FOR FURTHER INFORMATION CONTACT: James V. Lacy, Director, Office of Export Trading Company Affairs, International Trade Administration, 202/377-5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (Pub. L. 97-290) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. A certificate of review protects its holder and the members identified in it from private treble damage actions and from civil and criminal liability under Federal and state antitrust laws for the export conduct specified in the certificate and carried out during its effective period in compliance with its terms and conditions. Section 302(b)(1) of the Act and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a certficate should be issued. An original and five (5) copies should be submitted not later than (insert date 20 days after publication in the **Federal Register**) to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, Room 5618, Washington, D.C. 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). Comments should refer to this application as "Export Trading Certificate of Review, application number 85-00015."

Applicant: California Dried Fruit Export Trading Company ("CDFETC").

Application #: 85-00015.

Date Received: October 22, 1985.

Date Deemed Submitted: October 28, 1985.

Member: A & M Farm, Inc.; American Raisin Packers; Boghosian Raisin Packing Co., Inc.; Bonner Packing Company; California Prune Packing Co.; Caruthers Raisin Packing Company; Central California Raisin Packing Company; Champion Raisin International; Chooljian & Sons dba Del Rey Packing Company; Chooljian Bros. Packing Co., Inc.; Del Rey Packing Company; Enoch Packing Co.; Lion Enterprises, Inc. dba Lion Dehydrator, Lion Packing Company, and Lion Ranches; Lion Packing Company; National Raisin Company; Prize Exports, Inc.; Sun-Diamond Growers of California; Sun-Maid Growers of California; Sunsweet Growers Inc.; Tagus Ranch Packing; and Victor Packing, Inc.

Controlling Entity: None.

Summary of Application: CDFETC has submitted an application seeking certification for the following export-related activities:

Export Trade

California raisins, raisin products and products derived from raisins, and California prunes, prune products and products derived from prunes ("dried fruit").

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of Northern Marianna Islands, and the Trust Territory of the Pacific Islands), Canada, Mexico, all islands adjacent to these countries and all Caribbean islands north of the 12th Parallel but not

excluding those islands on the Continental Shelf of South America.

Export Trade Activities and Methods of Operation

CDFETC and its members desire certification to:

1. Dedicate the quantity of dried fruit that each member will make available for sale in the Export Markets, and determine whether any part of such quantity will be sold independently by the member, be sold in cooperation with some or all of the other members, or made available to the CDFETC for sale in the Export Markets.

2. Enter into agreements wherein CDFETC or one or more of the members agree to act in certain countries or markets as the members' exclusive or non-exclusive export sales representative for the quantity of dried fruit dedicated by each member for sale by CDFETC or any member in that country or market. In such agreements, (i) CDFETC or the member(s) acting as exclusive sales representative may agree not to represent any other supplier for sale in the Export Markets and (ii) members may agree that they will export the quantity dedicated for sale in these Export Markets exclusively through CDFETC or the member(s) acting as exclusive sales representative, and that they will not export independently of CDFETC, either directly or through other export intermediaries.

3. Refuse to deal with export intermediaries other than CDFETC and its members.

4. By agreement with CDFETC's distributors or agents in the Export Markets or with the members' distributors or agents in the Export Markets, or on the basis of CDFETC's own determination:

a. Establish the prices at which dried fruit will be sold in the Export Markets;

b. Establish target prices for sales of dried fruit by the members in the Export Markets, with each member being free to deviate from such target prices by whatever amount it sees fit;

c. Establish the quantity of dried fruit to be sold in the Export Markets;

d. Allocate the Export Markets or customers in the Export Markets among the members;

e. Refuse to quote prices for, or to market or sell, dried fruit in the Export Markets;

f. Engage in joint bidding or selling arrangements and allocate sales resulting from such arrangements among the members; and,

g. Engage in joint promotional activities aimed at developing existing or new export markets, such as advertising and trade shows.

5. Agree on the quantities and prices at which CDFETC and each member may sell dried fruit in the Export Markets, and may also agree on territorial and customer allocations in the Export Markets among the members.

6. Enter into exclusive and non-exclusive agreements appointing export intermediaries for the sale of dried fruit in the Export Markets. Such agreements may contain price, quantity, territorial, and customer restrictions.

7. Solicit non-member packers or handlers of dried fruit either to sell such products to the CDFETC for sale in the Export Markets or otherwise to combine those non-member products with those of some or all of the members for sale in the Export Markets.

8. Exchange and discuss information relating to or facilitating exporting, including but not limited to the following types of information:

a. Information about sales and marketing efforts, activities and opportunities for dried fruit for and in Export Markets, selling strategies for the Export Markets, sales for the Export Markets, contract and spot pricing in the Export Markets, projected demands in the Export Markets for dried fruit, customary terms of sale in the Export Markets, prices and availability of dried fruit from competitors for sales in the Export Markets, and specifications for dried fruit by customers in the Export Markets;

b. Information about what quality and quantity of, and from where and when, dried fruit would be available from the members for export;

c. Information about terms and conditions of contracts for sales in the Export Markets to be considered and/or bid on by CDFETC or the members;

d. Information about expenses specific to exporting to and within the Export Markets, including without limitation, transportation, trans- or intermodal shipments, insurance, inland freight to port, port storage, commissions, export sales, documentation and financing and customs, duties and taxes;

e. Information about U.S. and foreign legislation and regulations, including federal marketing order programs, affecting sales for the Export Markets; and,

f. Information about CDFETC's or its members' export operations, including without limitation, sales and distribution networks established by CDFETC or its members in the Export Markets, and prior export sales by members (including export price information).

9. Prescribe conditions for withdrawal of members from and admission of members to CDFETC.

10. Meet to engage in the activities described in paragraphs one through nine above.

Dated: November 7, 1985.

James V. Lacy,

Director, Office of Export Trading, Company Affairs.

[FR Doc. 85-26922 Filed 11-12-85; 8:45 am]

BILLING CODE 3510-DR-M

[A-357-405]

Antidumping Duty Order: Barbed Wire and Barbless Fencing Wire From Argentina

AGENCY: International Trade Administration, Import Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: In separate investigations concerning barbed wire and barbless fencing wire from Argentina (barbed wire), the United States Department of Commerce (the Department) and the United States International Trade Commission (the ITC) have determined that barbed wire from Argentina is being sold at less than fair value and that sales of barbed wire from Argentina are materially injuring a United States industry. Additionally, the Department found that "critical circumstances" did not exist with respect to barbed wire from Argentina. Therefore, based on these findings, all unliquidated entries, or warehouse withdrawals, for consumption of barbed wire from Argentina made on or after May 3, 1985, the date on which the Department published its "Preliminary Determination" notice in the Federal Register, will be liable for the possible assessment of antidumping duties. Further, a cash deposit of estimated antidumping duties must be made on all such entries, and withdrawals from warehouse, for consumption made on or after the date of publication of this antidumping duty order in the **Federal Register**.

EFFECTIVE DATE: November 13, 1985.

FOR FURTHER INFORMATION CONTACT: John J. Kenkel, Office of Investigations, International Trade Administration, United States Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230; telephone: (202) 377-5404.

SUPPLEMENTARY INFORMATION: The merchandise covered by this order is

barbed wire and barbless fencing wire from Argentina, which is currently classifiable under item numbers 642.0200 and 642.1105 of the Tariff Schedules of the United States Annotated (TSUSA).

In accordance with section 733 of the Tariff Act of 1930, as amended (the Act) (19 U.S.C. 1673b), on May 3, 1985, the Department published its preliminary determination that there was reason to believe or suspect that barbed wire from Argentina was being sold at less than fair value (50 FR 18906). We preliminarily determined that "critical circumstances" did not exist within the meaning of section 733(e) of the Act (19 U.S.C. 1673(e)). On September 23, 1985, the Department published its final determination that these imports were being sold at less than fair value and that "critical circumstances" did not exist with respect to barbed wire from Argentina (50 FR 38563).

On October 30, 1985, in accordance with section 735(d) of the Act (19 U.S.C. 1673(d)), the ITC notified the Department that such importations materially injure a United States industry.

Therefore, in accordance with sections 736 and 751 of the Act (19 U.S.C. 1673e and 1675), the Department directs United States Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act (19 U.S.C. 1673e(a)(1)), antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of barbed wire from Argentina. These antidumping duties will be assessed on all unliquidated entries of barbed wire entered, or withdrawn from warehouse, for consumption on or after May 3, 1985, the date on which the Department published its "Preliminary Determination" notice in the **Federal Register** (50 FR 18906).

On and after the date of publication of this notice, United States Customs officers must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the estimated weighted-averaged antidumping duty margin as noted below:

Manufacturers-Producers/Exporters	Weighted-Average (Percent)
Acindar Industria Argentina de Aceros, S.A.	69.02
All other Manufacturers/Producers Exporters	69.02

This determination constitutes an antidumping duty order with respect to barbed wire from Argentina, pursuant to section 736 of the Act (19 U.S.C. 1673e) and § 353.48 of the Commerce Regulations (19 CFR 353.48). We have deleted from the Commerce Regulations, Annex I of 19 CFR Part 353, which listed antidumping findings and orders currently in effect. Instead, interested parties may contact the Office of Information Services, Import Administration, for copies of the updated list of orders currently in effect.

This notice is published in accordance with section 736 of the Act (19 U.S.C. 1673e) and § 353.48 of the Commerce Regulations (19 CFR 353.48).

Gilbert B. Kaplan,

Acting Deputy Assistant Secretary for Import Administration.

November 6, 1985.

[FR Doc. 85-26978 Filed 11-12-85; 8:45 am]

BILLING CODE 3510-DS-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Import Limit for Certain Cotton Textile Products Produced or Manufactured in Israel

November 7, 1985.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on November 13, 1986. For further information contact Ann Fields, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce (202) 377-4212.

Background

On November 4, 1985 the Governments of the United States and Israel exchanged letters on an arrangement dating from September 1, 1985 and extending through March 31, 1986. The arrangement establishes a limit of 750,000 numbers for cotton sheets in Category 361, produced or manufactured in Israel and exported during the seven-month period which began on September 1, 1985 and extends through March 31, 1986. The letter from the Chairman of the Committee for the Implementation of Textile Agreements which follows this notice cancels and supersedes the previously established level for this category (See 50 FR 43761) and directs the Commissioner of Customs to prohibit entry into the United States for consumption and withdrawal from warehouse for consumption of cotton sheets in Category 361 in excess of the newly agreed seven-month limit.

The limit has not been adjusted to account for imports of merchandise in this category, exported on and after September 1, 1985. These charges will be made as the date become available.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1985).

Walter C. Lenahan,

Chairman, Committee for the Implementation of Textiles Agreements.

November 7, 1985.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury, Washington, D.C. 20229

Dear Mr. Commissioner: This directive cancels and supersedes the directive of October 24, 1985 which directed you to prohibit entry of cotton textile products in Category 361, produced or manufactured in Israel in excess of the designated limit.

Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), pursuant to the arrangement of November 4, 1985, between the Governments of the United States and Israel, and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on November 13, 1985, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textile products in Category 361 produced or manufactured in Israel and exported through March 31, 1986, in excess of 750,000 numbers.[1]

Textile products in Category 361 which have been exported to the United States prior to September 1, 1985 shall not be subject to this directive.

Textile products in Category 361 which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1)(A) prior to the effective date of this directive shall not be denied entry under this directive.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983, (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR

[1] The limit has not been adjusted to reflect any imports expired after August 31, 1985.

44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1985).

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553 (a)(1).

Sincerely,

Walter C. Lenahan,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 85-26945 Filed 11-12-85; 8:45 am]

BILLING CODE 3510-DR-M

CONSUMER PRODUCT SAFETY COMMISSION

Notification of Request for Extension of Approval of Information Collection Requirements—Requirements for Electrically Operated Toys

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1981 (44 U.S.C. 3501 *et seq.*), the Consumer Product Safety Commission has submitted a request to the Office of Management and Budget for an extension, through December 31, 1988, of its approval of collection of information requirements in 16 CFR Part 1505. That rule requires the manufacturers (including importers) of certain electrical toys and other children's products to provide warning and identification labeling and to establish and maintain a quality assurance program. In addition , the manufacturers must make, keep, and maintain for three years records of sales and distribution, material and production specifications, a description of the quality assurance program, and the results of all inspections and tests conducted.

The purposes of these reporting requirements are to reduce the risks to children of electrocution, electric shock, electrical burns, and thermal burns associated with electrical children's products and to help determine the extent to which manufacturers are complying with 16 CFR Part 1505.

Information About the Requested Extension of Approval of Requirements for Collection of Information

Agency address: Consumer Product Safety Commission, 1111 18th Street, NW., Washington, DC 20207.

Title of information collection: Requirements for Electrically Operated Toys or Other Electrically Operated Articles Intended for Use by Children, 16 CFR 1505.4(a)(3).

Type of request: Extension of approval.

Frequency of collection: Recordkeeping, plus occasional reporting at the request of the Commission's compliance staff.

General description of respondents: Manufacturers of electrically operated toys and other children's articles.

Estimated number of respondents: 40.

Estimated average number of hours per response: 40 for keeping records and 160 for conducting tests, per year.

Estimated number of hours for all respondents: 8000 per year.

Comments. Comments on this requested extension of approval of information collection requirements should be addressed by Andy Valez-Rivera, Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503; telephone: (202) 395-7340. Copies of the request for extension of information collection requirements are available from Francine Shacter, Office of Budget, Planning, and Program Evaluation, Consumer Product Safety Commission, Washington, DC 20207; telephone: (301) 492-6529.

This is not a proposal to which 44 U.S.C. 3504(h) is applicable.

Dated: November 6, 1985

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 85-26928 Filed 11-12-85; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF EDUCATION

National Institute of Handicapped Research; Funding Priorities

AGENCY: Department of Education.

ACTION: Notice of Proposed Funding Priorities for Fiscal Year 1986.

SUMMARY: The Secretary of Education proposes funding priorities for research activities to be supported under some programs of the National Institute of Handicapped Research (NIHR) in Fiscal Year 1986. NIHR is required under the Rehabilitation Act of 1973 as amended, to develop a long-range research plan that identifies goals for rehabilitation research and to determine funding priorities that will facilitate the support of these activities within available resources. These proposed priorities are derived from the NIHR Long-Range Plan and are articulated within the goals, objectives, and research activities specified in the Plan.

Authority for the research program of NIHR is contained in section 204 of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602 and by Pub. L. 98-221.

DATE: Interested persons are invited to submit comments or suggestions regarding the proposed priorities on or before December 13, 19085.

ADDRESS: All written comments and suggestions should be sent to Betty Jo Berland, National Institute of Handicapped Research, Department of Education, 400 Maryland Avenue, SW., Room 3070, Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Betty Jo Berland, National Institute of Handicapped Research. Telephone (202 732-1139; deaf and hearing impaired individuals may call (202) 732-1198 for TTY services.

SUPPLEMENTARY INFORMATION: Under this program, awards are made to public and private agencies and organizations, including institutions of higher education. NIHR can make awards for up to 60 months.

The purpose of the awards is for planning and conducting research, demonstrations, and related activities which have a direct bearing on the development of methods, procedures, and devices to assist in providing vocational and other rehabilitation services to handicapped individuals, especially those with the most severe handicaps.

NIHR regulations (46 FR 45300, September 10, 1981, as amended March 12, 1984 at 49 FR 9324) authorize the Secretary to establish research priorities by reserving funds to support particular research activities (see 34 CFR 351.32)

NIHR invites public comment on the merits of the proposed priorities both individually and collectively, including suggested modifications to the proposed priorities. Comments might also cite factors which support the importance of a priority to handicapped individuals and other interested parties.

Each priority is proposed under the program authority that NIHR believes to be most appropriate. These programs are described below. The public is also invited to comment on the appropriateness of the program mechanism selected for a particular priority (i.e., whether certain research objectives are better accomplished by centers or by other grantees as discrete projects).

This notice does not solicit application proposals or concept papers. The final priorities will be established

on the basis of public comment, the availability of funds, and any other relevant Departmental considerations. These final priorities will be announced in an application notice in the Federal Register. That notice will also solicit grant applications and set the closing date.

NIHR intends to publish in a separate issue of the Federal Register three proposed priorities for the Research and Training Center Program. Research and other activities which NIHR intends to procure through contracts will be announced by Requests for Proposals published in the *Commerce Business Daily*.

The publication of these proposed priorities does not bind the United States Department of Education to fund projects in any or all of these research areas. Funding of particular projects depends on both the availability of funds and on final priorities established following responses to this notice.

The Department of Education has consulted with the Deartment of Health and Human Services in developing the priority on financing home care for severely disabled and chonically ill children.

The following eight proposed priorities represent areas in which NIHR proposes to support research and related activities through grants or cooperative agreements in two programs, the Research and Demonstration Program and the Knowledge Dissemination and Utilization Program. Following are brif descriptions of these two programs.

Research and Demonstration Projects support research and/or demonstrations in single project areas on problems encountered by handicapped individuals in their daily activities. These projects may conduct research on rehabilitation techniques and services, including analysis of medical, industrial, vocational, social, sexual, psychiatric, psychological, economic, and other factors affected the rehabilitaiton of handicapped individuals.

Knowledge Dissemination and Utilization Projects support activities to ensure that rehabilitation knowledge generated from projects and centers funded by NIHR and others is fully utilized to improve the lives of handicapped persons.

Priorities for Research and Demonstration Projects (6)

Transition from School to Work for Deaf Youth

There are approximately 400 identifiable, mainstream secondary education programs, as well as approximately 70 (private or public) residential school programs serving deaf and hard-of-hearing students. Some observers note that there is a significant problem in providing these students a transition into the work force, whether directly into the job market or into vocational rehabilitation services. However, there is currently no national reserch documenting experiences and identifying superior strategies.

A research and demonstration project in this area is proposed to—

- Study the vocational rehabilitation aspects of planning and providing transitional assistance to deaf and hard-of-hearing students in their movement from various types of educational programs into the work force;
- Identify, in existing programs, those variables associated with successful transitions, reviewing for such factors as the following: early identification and referral to vocational rehabilitation programs; joint Individual Education Plans—Individual Written Rehabilitation Plans and cooperative planning between the educational and vocational rehabilitation agencies; and other methods used in various types of secondary and postsecondary programs serving deaf and hard-of-hearing students.
- Study a representative sample of deaf and hard-of-hearing students with secondary disabilities such as blindness, developmental disabilities, and mental handicaps, to assess transitional outcomes and factors associated with successful transitions; and
- Analyze the variations in cooperative transitional programs involving State vocational rehabilitation agencies and special education programs serving deaf and hard-of-hearing students; determine which models provide the best results for clients and their families; and determine the most effective methods for disseminating the findings to the appropriate parent organizations, and rehabilitation and special education personnel.

Late Effects of Poliomyelitis

There are an estimated 250,000 polio survivors between the ages of 38 and 55 in the United States who are experiencing additional complications that are emerging as late effects of the disease. Based on the findings of two international symposia and the Task Force on Post-Polio Problems of the American Congress of Rehabilitation Medicine, there is an immediate need for further research on late-developing debilitating problems affecting polio survivors. These late effects may cause loss of motor function and reversal of rehabilitation gains. Research is needed to develop methods to prevent additional complications as well as to treat those that do occur. Rehabilitation medicine practitioners and treatment teams need definitive new knowledge on effective interventions in these areas.

A research and demonstration project in this area is proposed to—

- Study the etiology, natural history, and medical management of progressive post-polio muscular atrophy;
- Investigate the response to exercise of partially enervated muscles in chronic polio and post-polio syndromes;
- Conduct clinical research into the mechanism of rapid fatigue and generalized exhaustion;
- Study techniques of improved medical management of progressive musculoskeletal conditions, such as chronic muscle strain, myofascitis, tendonitis, and bursitis; and
- Conduct studies on the metabolism of the motor unit in subjects undergoing progressive motor unit dysfunction.

Financing Home Care for Seriously Disabled and Chronically Ill Children

One goal of the Office of Special Education and Rehabilitative Services is to promote the use of least restrictive environments for living, education, work, and social life for all disabled people. Most interested parties, including parents, physicians and allied health personnel, educators, policymakers, and researchers, agree on the benefits of rearing disabled children at home with their families. However, financial considerations currently are a major obstacle to caring for severely disabled children in their own homes, and current systems of financial support for health and habilitative care provide additional disincentives to maintaining these children in the least restrictive environments. Federal and State governments and third-party payers such as insurance companies, as well as parents and program administrators, must be involved in efforts to develop and implement mechanisms to provide the necessary financial support for care in the home and community.

A research and demonstration project in this area is proposed to—

- Investigate the variations in coverage by major third-party payers, including coverage of psychosocial support services for disabled children and their families;
- Develop a financing model, involving public, private, and voluntary resources, which supports home and community-based services;
- Develop a model for providing families with financial counseling

regarding reimbursement procedures and other options available for financing home care and other services;

• Investigate, in consultation with the Department of Health and Human Services, the potential impact of applying Diagnostic Related Groups to pediatric services on reimbursement for care of disabled and chronically ill children at home and in institutions;

• In consultation with the Department of Health and Human Services, analyze the use of existing Title XIX waiver programs and develop strategies to encourage States to adopt waiver programs;

• Develop a plan to facilitate the nationwide dissemination and utilization of the research findings, including a national conference of relevant parties to discuss and develop strategies to implement the research findings.

Improved Functioning in Families with Learning Disabled Children

Low self-esteem, lack of social skills, and disorganization are characteristics often found in children with severe learning disabilities. Disruptive and other behaviors associated with these characteristics frequently lead to family dysfunction, and thus inadequate care for the learning disabled child. Many parents of learning disabled children are not well equipped with the knowledge, skills, or experience to help with their childrens' behavioral and organizational problems. There is a need to assist these parents and children to develop family coping skills, but there is an inadequate knowledge base on which to develop intervention strategies.

A research and demonstration project in this area is proposed to—

• Develop and evaluate strategies that would enable families to teach appropriate social skills to severely learning disabled children;

• Develop and evaluate strategies for training that would enable families to cope with behavioral problems evidenced by severely learning disabled children; and

• Establish a resource center which will promote the use of new knowledge in management of the unique behavior deficits of learning disabled children by disseminating information to parents.

Technology for Sensory Devices

Past research in the area of assistive devices for deaf people, supported by NIHR and other Federal agencies, has been directly primarily toward aiding deaf people to hear. Recent NIHR-sponsored studies have indicated that there is a need for more research to develop devices and systems to provide input for the communication of sounds through other senses. NIHR proposes to study ways in which the Federal government and the private sector can cooperate to most effectively apply modern technological advances to minimize communication barriers for deaf individuals in the home, workplace, and community.

A research and demonstration project in this area is proposed to—

• Explore the feasibility of influencing manufacturers of products for the general market to adapt their products and devices to make them accessible to deaf and severely hard-of-hearing people;

• Determine the most feasible approach to promote and maintain a continuous activity of developing and enhancing special aids, to ensure that the benefits of new technology will be regularly incorporated in sensory aids;

• Explore the feasibility of establishing alternative mechanisms for financing the purchase of general aids and special sensory aids that meet the needs of deaf and severely hard-of-hearing individuals;

• Identify emerging technology that has potential to reduce or eliminate some of the communication barriers confronting deaf people; and

• Assess the needs for sensory aids for deaf people, focusing on the needs for aids incorporating recent technological developments.

Housing Adaptations to Promote Less Restrictive Environments

It is often extremely difficult for severely disabled people to live independently in their own homes or other private residential facilities. In many cases housing is not modified or adapted to the special physical needs of the individual. While a number of advances have been made in suitable architectural designs for homes and offices, research and development are needed to improve technology to enhance the independence of the disabled user.

A research and demonstration project is proposed in this area to—

• Develop retrofitting techniques to modify present housing designs to serve the needs of disabled persons;

• Design environmental control systems to enable disabled individuals to control temperature, lights, appliances, security systems, and other household instruments; and

• Develop communication systems to permit monitoring of critical health conditions from a remote central location and to permit disabled people needing assistance to signal a central unit.

Priorities for Knowledge Dissemination and Utilization Projects (2)

Regional Diffusion Networks

There is a need to promote the widespread use of new, validated practices and exemplary programs in selected priority areas in order to improve the service delivery system for disabled individuals. NIHR proposes to address this need by establishing one or more regional diffusion networks similar to those which are now operating in the West (Regions VI and IX). Priority areas for diffusion efforts during the period of this project will include school-to-work transition programs which include learning disabled individuals and programs which promote least restrictive environments for disabled people.

A knowledge dissemination and utilization project is proposed in this area to—

• Develop criteria for identifying exemplary programs, and develop information collection instruments which include measurements related to the identified criteria;

• Solicit nominations of exemplary programs in the priority areas from program operators, consumer organizations, and other relevant parties in the selected regions;

• Develop and implement a procedure to select the most promising programs for further consideration and arrange independent peer reviews of those programs to select exemplary programs for diffusion;

• Develop public relations and marketing approaches to make the wide audience of rehabilitation service providers and special educators aware of the exemplary programs and stimulate their interest in adopting/adapting similar models, assisted by the diffusion network;

• Facilitate the exchange of technical assistance between the exemplary program and the requesting adopter program; and

• Maintain appropriate data on the diffusion network to support an evaluation of its effectiveness.

Policy Research Utilization Center

Numerous agencies and organizations have undertaken research and other studies relevant to disability policy issues. To promote more effective use of knowledge in the development of disability policy, policymakers and others need access to this knowledge base. There is a need to identify relevant policy research, analyze it for reliability and applicability, and categorize and format it for easy access

and use by decisionmakers. Research related to policies on rehabilitation and employment of disabled persons will have first priority in this effort.

A knowledge dissemination and utilization project in this area is proposed to—

- Identify that research supported by NIHR and other agencies which has policy implications, focusing particularly on studies on: the economics of disability; work disincentives; community-based care; habilitation of handicapped children; and the training and deployment of professionals in rehabilitation-related disciplines;
- Develop a mechanism to obtain input from NIHR, the National Council on the Handicapped, and other Federal agencies managing disability-related programs on other policy issues which are of significant interest and in which there should be reviews of research during the project period;
- Evaluate and summarize available research documents in these areas, and disseminate summaries and relevant source documents to agencies which the project selects as appropriate recipients;
- Develop a directory of agencies and organizations active in the area of disability policy research; and
- Identify gaps in policy research in areas reviewed for the study.

Invitation to Comment

Interested parties are invited to submit comments and recommendations regarding these priorities. Written comments and recommendations may be sent to the address given at the beginning of this document. All comments received on or before December 13, 1985 will be considered before the Secretary issues final priorities. All comments submitted in response to these proposed priorities will be available for public inspection during and after the comment period in Room 3070, Mary E. Switzer Building, 330 C Street, SW., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

(20 U.S.C. 761a, 762)

(Catalog of Federal Domestic Assistance No. 84.133, National Institute of Handicapped Research)

Dated: November 7, 1985.

William J. Bennett,

Secretary of Education.

[FR Doc. 85-26955 Filed 11-12-85; 8:45 am]

BILLING CODE 4000-01-M

Office of Special Education and Rehabilitative Services

Projects for Initiating Special Recreation Programs for Handicapped Individuals

AGENCY: Department of Education.

ACTION: Notice of Proposed Funding Priority for Fiscal Year 1986.

SUMMARY: The Secretary proposes an annual funding priority for grants for Initiating Special Recreation Programs for Handicapped Individuals. The Secretary proposes a single priority to support only those projects that integrate socialization and recreational opportunities for both handicapped and non-handicapped individuals. This is considered the area of greatest need during Fiscal Year 1986.

DATES: Comments must be received on or before December 13, 1985.

ADDRESSES: All written comments and suggestions should be sent to Dr. James W. Moss, Associate Commissioner, Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services, Room 3030 Mary E. Switzer Building, Department of Education, 400 Maryland Avenue, SW., MS 2312, Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Frank S. Caracciolo, Telephone: (202) 732-1340.

SUPPLEMENTARY INFORMATION: Grants for Initiating Special Recreation Programs for Handicapped Individuals are authorized by Section 316 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 777f). Program regulations are established at 34 CFR Part 378. The purpose of the Special Recreation Programs for Handicapped Individuals is to support projects which initiate recreational activities for handicapped individuals.

Eligible Applicants

State and public or other nonprofit agencies and organizations are eligible to apply for grants under this program.

Funds Available

Final action on the fiscal year 1986 appropriation has not been taken, and the Department has not requested funds for this program in fiscal year 1986. However, in fiscal year 1985 the Congress appropriated $2,100,000 for this program. Any funds appropriated for fiscal year 1986 will be used to support new special recreation projects which address the proposed priority described below.

Proposed Priority

In accordance with Education Department General Administrative Regulations (EDGAR) at 34 CFR 75.105(c)(3), the Secretary proposes to give absolute preference as described in the subsequent subsection entitled, "Projects to be Funded," to applications submitted in fiscal year 1986 in response to the single priority to be established.

All applications will be evaluated according to criteria which appear in program regulations at 34 CFR 378.31. The single proposed priority is:

Intergrated Recreation

The purpose of this proposed priority is to support only those projects that integrate socialization and recreational opportunities for both handicapped and non-handicapped individuals. The Secretary anticipates that this proposed priority will stimulate greater involvement and participation of handicapped persons in existing local and national recreational activities and decrease the possibility of restricted and segregated recreational programs. In addition, there should be less duplication of resources for recreation.

Projects to be Funded

Applicants for new projects under this program will be awarded funds in fiscal year 1986 to the extent they are available in the single proposed priority area.

Invitation to Comment

Interested perons are invited to submit comments and recommendations regarding this proposed priority. Written comments and recommendations may be sent to the address given at the beginning of this document. All comments received on or before the 30th day after publication of this document will be considered before the Secretary issues a final priority. All comments submitted in response to this proposed priority will be available for public inspection, during and after the comment period, in Room 3030 Switzer Building, 330 C Street, SW., Washington, D.C. between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

(Catalog of Federal Domestic Assistance No. 84.128 Initiating Special Recreation Programs for Handicapped Individuals)

(29 U.S.C. 777f)

Dated November 7, 1985.

William J. Bennett,

Secretary of Education.

[FR Doc. 85-26956 Filed 11-12-85; 8:45 am]

BILLING CODE 4000-01-M

Cancellation of Public Meeting

SUMMARY: The meeting of the National Advisory Committee on Accreditation and Institutional Eligibility which was scheduled for November 18 and 19 has been cancelled.

FOR FURTHER INFORMATION CONTACT: Morris L. Brown, Director, Division of Eligibility and Agency Evaluation, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue, SW (Room 3030, ROB-3), Washington, D.C. 20202 (202/245-9703).

Signed at Washington, D.C. on November 12, 1985.

Kenneth D. Whitehead,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 85-27135 Filed 11-12-85; 10:52 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Bonneville Power Administration

Record of Decision; Eugene-Medford 500-kV Transmission Line From Alvery Substation to Spencer Switching Station

AGENCY: Bonneville Power Administraion (BPA), DOE.

ACTION: Record of Decision.

SUMMARY: The U.S. Department of energy, Bonneville Power Administration, and the Pacific Power and Light Company (PP&L) proposed to build 500-kV transmission facilities from Eugene to Medford in the State of Oregon. The proposal was based on a need to reliably serve growing electrical loads in southern Oregon and northern California. The project was also proposed to satisfy a future need to upgrade service in the Eugene area.

Several alternatives were studied to meet the need. The alternatives, including the proposed action for service from Eugene to Medford, were analyzed in the May 1983 Final Enironmental Impact Statement (EIS) titled "Proposed Eugene-Medford 500 kV Transmission Line." The EIS was prepared by the U.S. Department of the Interior, Bureau of Land Management (BLM), as lead agency and BPA as cooperating agency. BPA's proposed action was fully discussed in the EIS, which has been adopted by DOE.

This Record of Decision (ROD) describes BPA's decision to build a 2-mile 500-kV transmission line from the existing BPA Alvey Substation to the PP&L Spencer Switching Station site near Eugene. A companion ROD issued by BLM in December 1984 describes BLM's decision to grant the right-of-way on public lands for a 133.2-mile PP&L transmission line from the Spencer Switching Station site south to Medford. Together the two segments of line provide 500-kV transmission service from Eugene to Medford.

Decision: BPA has decided to proceed with the alternative that provides a single-circuit 500-kV transmission line from Alvery Substation to the Spencer Switching Station. The 2-mile route will require 30 acres of addition right-of-way. Terminal switching facilities for the 550-kV line will be added at Alvey Substation. The estimated cost of this option is $5.5 million.

The selected alternative is identified in the Final EIS as Alternative 4, the New Preferred Alternative, and in the Draft EIS as Option C.

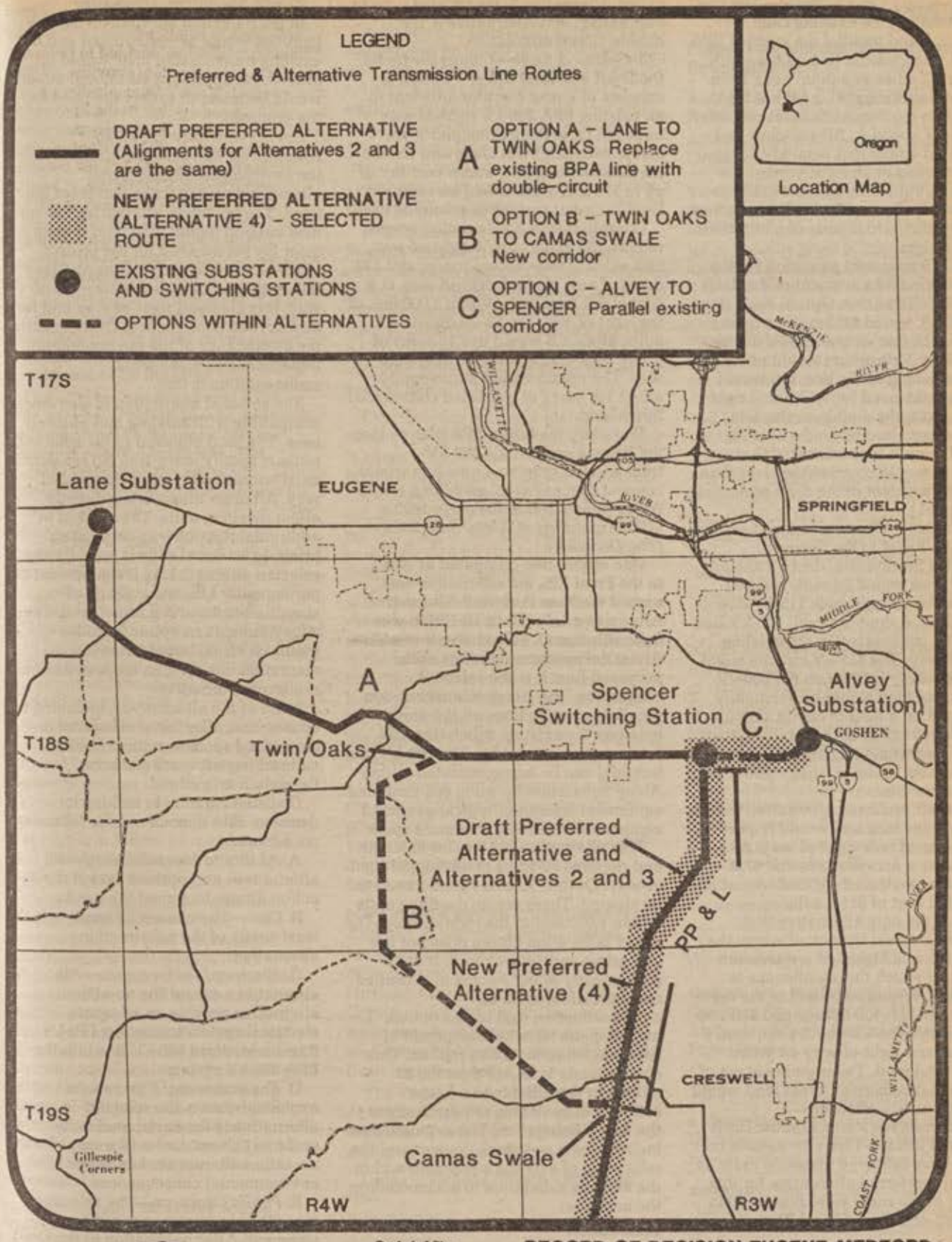
SUPPLEMENTARY INFORMATION:

Alternatives: In arriving at a decision, BPA evaluated a number of alternative and options. In some, the line would have originated at the BPA Lane Substation. One originated at Alvey and one involved no action. Following a brief description of each, and a map illustrating the alternative routes. The names for the alternatives here are the same as those used in the text of the Final EIS.

A. *Originating at Lane Substation*—The alternatives that originated at Lane Substation are described below.

1. *Draft Preferred Alternative*—The preferred alternative from the Draft EIS consists of two segments: from the Lane Substation to Twin Oaks and from Twin Oaks to the Spencer Switching Station.

BILLING CODE 6450-01-M



RECORD OF DECISION EUGENE-MEDFORD 500 kV TRANSMISSION LINE FROM ALVEY SUBSTATION TO SPENCER SWITCHING STATION

BILLING CODE 6450-01-C

Lane—Twin Oaks segment—The line would begin at the existing Lane Substation and parallel the existing BPA 230–kV transmission line on the south side for 7.5 miles to a point near Twin Oaks, where the existing BPA 115–kV lines (from the Eugene Substation) enter the 230-kV corridor. All switches and associated equipment would be located in the existing equipment yard at the BPA Lane Substation. BPA would construct the Lane—Twin Oaks segment using its standard double circuit 500-kV tower design.

(The EIS proposed an option for the Lane—Twin Oaks segment of the draft preferred alternative. Option A, as it was called, would replace an existing 230-kV BPA line with a 500-kV double circuit line. This option would not affect the total length of the line, but would eliminate the need for additional right-of-way since the double circuit line could be constructed on the existing right-of-way. It was estimated that Option A would cost $400,000 less than the same segment of the draft preferred alternative.)

Twin Oaks—Spencer segment—From Twin Oaks east to the Spencer Switching Station site, the two existing 115-kV lines would be removed and replaced by a single pole 115-kV double circuit line. A double circuit 500-kV line would be constructed in the existing right-of-way. The 115-kV circuits might be temporarily located on the 500-kV towers, but they would be eventually supported on a double circuit single pole. Construction of the double circuit 115-kV line would be needed to have enough room in the existing right-of-way for the new line.

The draft preferred alternative would be 11.5 miles long and would require 113.6 acres of new right-of-way, 2.3 miles of new access roads and 47.2 acres of new cleared right-of-way at an estimated cost of $11.9 million.

This is the only alternative that included a visual impact, of which the significance is high, and a recreation impact, of which the significance is moderate. Within 1,000 feet of the right-of-way are 115–130 houses and 230–290 apartments. The alternative required 6 acres of new right-of-way on prime agricultural land. Twenty-nine acres of classified commercial forest land would be permanently affected.

2. *Alternatives 2 and 3* (in the Draft and Final EIS's)—Two alternatives that would have followed the same route as the draft preferred alternative for this portion of the route were discussed in the Draft and Final EIS's.[1] They were called Alternative 2, the parallel alternative, and Alternative 3, the double circuit alternative.

3. *Option B, Lane—Camas Swale* (in the Draft and final EIS's)—Option B consists of a new corridor adjacent to an existing BPA 230-kV right-of-way between Lane Substation and Twin Oaks. Between Twin Oaks and Camas Swale switching site, a new corridor of up to 175 feet wide would be acquired. Double circuit structures would be used.

Overall, this 14.2 mile option would require 259 acres of new right-of-way, 18.3 miles of new access roads, and 133 acres of new cleared right-of-way at a cost of $11.9 million. Within 1,000 feet of the right-of-way are 16–20 dwelling units. Option B would use 32 acres of prime agricultural land for new right-of-way. The option would permanently affect 106 acres of classified commercial forest land.

To satisfy the future BPA plan to loop the Eugene area with a 500-kV transmission system, a new line would connect Camas Swale switching site to Alvey Substation in the early 1990's.

B. *Originating at Alvey Substation—(The Decision)*

One alternative originated at Alvey. In the Final EIS, the alternative was named the New Preferred Alternative, Alternative 4. In the Draft EIS, it was called Option C. This alternative makes Alvey the northern terminus of the proposed line. It is the selected alterantive. The Alvey-Spencer option parallels existing lines on the north between the existing substation and future switching station. The 500-kV line terminal can be accommodated within Alvey Substation by using gas-insulated equipment instead of typical overhead equipment which requires more space.

This alternative is 2.0 miles in length and requires 30 acres of additional right-of-way. Of this, 16 acres would need to be cleared. There are no dwelling units within 1,000 feet of the right-of-way. The Alvey Substation option does not use any prime agricultural land. It does permanently affect 5 acres of classified commercial forest land.

The estimated cost of this option, including the terminal equipment at Alvey Substation, is $5.5 million. This cost estimate is higher than the $3 million in the EIS due to a better estimate of switching requirements at the Alvey Substation. The estimate now includes new switching devices and the relocation of existing equipment within the existing substation to accommodate the new line.

C. *The No-Action Alternative*

In the no-action alternative, no new facilities would be constructed and no existing transmission lines would be altered. No special or additional actions would be taken to satisfy the need for the proposal.

Environmentally Preferred Alternative. The selected alterantive is the environmentally preferred alterantive among those that meet the need. The no-action alternative has no new environmental effect but it does not meet the stated need for the project.

The alternative originating at Alvey Substation requires less new right-of-way, less cleareed right-of-way and less access road construction. Consequently, the significance of the environmental impacts of soil erosion and sedimentation is less.

The selected alternative is also more compatible with existing and planned uses. The land adjacent to the selected route is mainly industrial. No residences exist within 1,000 feet of the right-of-way. All other alternatives directly affect dwelling units. The amount of additional right-of-way acreage on prime agricultural soils is least for the selected alternative as is the amount of permanently affected acreage of classified commercial forest land. The Alvey Substation option includes neither a visual impact area nor a recreation impact area as does the draft preferred alternative.

None of the alternatives, including the chosen one, affect an endangered or threatened species, critical habitat, cultural resource, coastal zone, floodplain or wetland.

Decision Factors: In making its decision, BPA considered the following six factors.

A. *Ability to Meet the Need*—All alternatives and options except the no-action alternative meet the need.

B. *Cost*—The chosen alternative is the least costly of the construction alternatives.

C. *Electrical Performance*—All alternatives except the no-action alternative provide an adequate electrical system to connect PP&L's Eugene-Medford 500-kV line into the BFA 500-kV system.

D. *Environmental Effects*—As explained above, the selected alternative is the environmentally preferred alternative and, except for the no-action alternative, has fewer environmental consequences.

E. *Public Concerns*—The selection was made in response to public comment. After publication of the Draft EIS, extensive public comment was received which greatly influenced the

[1] The difference between the alternatives occurred further south, on PP&L's part of the line. Those alternatives are discussed in the companion Record of Decision that was prepared by the Bureau of Land Management.

configuration of the preferred alternative (Alternative 4) of the Final EIS. That is the alternative that has been chosen.

F. *Consistency with the Actions of Other Governmental Agencies*—The decision is consistent with recommendations of other governmental agencies. The Oregon Energy Facility Siting Council (EFSC) issued a site certificate for PP&L's proposed transmission line in September of 1982. The site certificate reflected public comment on the Draft EIS as augmented by testimony under Oregon administrative procedure. EFSC granted the site certificate to PP&L contingent upon construction of the Alvey option rather than the Lane-Spencer option as recommended by the Draft EIS.

The City of Eugene examined the transmission alternatives and adopted findings on the consistency of these alternatives with local plans. The findings supported the selected alternative as the most consistent with these plans.

Mitigation: Many environmental considerations that have been applied in siting the line are *best resource management practices*. While they are an integral part of the siting and mitigation process, they are not repeated here as mitigation measures. Only those actions necessary to reduce residual impacts that cannot otherwise be avoided are included.

Several means of mitigating environmental impacts of the project are adopted. Adopting these mitigation measures insures that all practicable means have been used to protect the environment from harm. It also insures that BPA will follow its mandates for land management as set forth in law, regulation, and policy.

Certain mitigation measures are *standard BPA policy* and are incorporated into BPA's standard construction specifications. They are intended to reduce noise, electric and magnetic effects, soil erosion, land use conflicts, impacts on vegetation, and impacts on wildlife and their habitat. They are also designed to protect environmental quality and cultural and natural resources. A noxious weed survey of the proposed route will be undertaken both before and after construction and measures will be taken during construction to minimize infestation.

Other adopted measures will be included in the project's *construction specifications and mitigation plan*. They will minimize right-of-way clearing consistent with safe, reliable operation of the line; control access road development; control soil erosion and sedimentation; coordinate both clearing and tower and road locations; schedule construction as necessry to avoid sensitive wildlife habitat and poor soil conditions; otherwise reduce or avoid effects on wildlife or their habitat and impacts on hunting opportunity; reduce visual intrusion; and reduce disturbance of desirable vegetation.

In addition, one *specific mitigation measure* has been adopted for the Alvey-Spencer segment of the line. The visibility of conductors will be mitigated through the use of non-reflective conductors from Alvey to Spencer. The additional cost, $10,000, has been included in the previously mentioned project costs.

One measure was considered and not adopted. The selected alternative, which is single circuit, requires additional land acquisition and therefore has an added impact on land use. The Final EIS explained that the need for additional right-of-way in the Alvey-Spencer corridor could be eliminated by using double circuit structures.

Double circuit structures could replace the two existing 115-kV wood pole structures and a double circuit structure could be used for the proposed 500-kV line. The primary reasons for not building double circuit at this time are load growth and cost. Another reason is the greater visibility of the double circuit structures.

Monitoring and Enforcement: Because the special mitigation measure for this project will be included in the construction specifications, no special monitoring and enforcement will be necessary.

FOR FURTHER INFORMATION CONTACT: Anthony R. Morrell, Environmental Manager, Bonneville Power Administration, P.O. Box 3621-SJ, Portland, Oregon 97208; (503) 230-5136. Copies of this Record of Decision are being sent to agencies, organizations and individuals who commented on the Draft and Final EIS's.

The Federal decisionmaker, by signing an original copy of this Record of Decision, is making a decision to the extent of the agency's jurisdiction.

Issued in Portland, Oregon, October 28, 1985.

Peter T. Johnson,

Administrator.

[FR Doc. 85-26906 Filed 11-12-85; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

Proposed Remedial Order; Listo Petroleum, Inc.

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of Proposed Remedial Order to Listo Petroleum, Inc.

SUMMARY: Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives Notice of a Proposed Remedial Order which was issued to Listo Petroleum, Inc. (Listo) doing business at 12491 I-45 North Freeway, Suite 815, Houston, Texas 77060. This Proposed Remedial Order alleges that Listo charged prices in excess of its actual purchase price in violation of 10 CFR 212.186, 210.62(c) and 205.202 during the period December 1979 through July 1980 in the amount of $7,503,039.35.

A copy of the Proposed Remedial Order, with confidential information, if any, deleted, may be obtained from: U.S. Department of Energy, Economic Regulatory Administration, ATTN: Sandra K. Webb, Director, One Allen Center, Suite 610, 500 Dallas Street, Houston, Texas 77002.

Within fifteen (15) days of publication of this notice any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, in accordance with 10 CFR 205.193.

Issued in Houston, Texas, on the 30th day of September, 1985.

Sandra K. Webb,

Director, Houston Office, Economic Regulatory Administration.

[FR Doc. 85-26927 Filed 11-12-85; 8:45 am]

BILLING CODE 6450-01-M

[ERA Docket No. 85-25-NG]

Natural Gas Imports; St. Lawrence Gas Co., Inc.; Application To Amend Authorization To Import Natural Gas From Canada

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of application to extend the term of existing authorization to import natural gas from Canada.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice of receipt on October 16, 1985, of an application from St. Lawrence Gas Company, Inc. (St. Lawrence) to amend its existing

import authorization to extend the term during which it can import natural gas from Canada at the current maximum daily volume of 50,000 Mcf from November 1, 1985, through the contract year ending October 31, 1987. The gas will be imported from Niagara Gas Transmission Limited (Niagara). St. Lawrence states that the contract base price is $4.40 (U.S.) per MMBtu, however, most if not all of its incremental, best-efforts volumes (up to 7,000 Mcf per day) will be purchased from Niagara at $3.40 (U.S.) per MMBtu under the Canadian Volume Related Incentive Price (VRIP) program.

DATE: Protests, motions to intervene or notices of intervention, as applicable, and written comments are to be filed no later than 4:30 p.m., on December 13, 1985.

FOR FURTHER INFORMATION CONTACT:

Edward J. Peters, Jr., Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Forrestal Building, Room GA–098, 1000 Independence Avenue, SW., Washington, D.C. 20585, (202) 252–8162.

Diane J. Stubbs, Office of Attorney General, Natural Gas and Mineral Leasing, Forrestal Building, Room 6E–042, 1000 Independence Avenue, SW., Washington, D.C. 20585, (202) 252–6667.

SUPPLEMENTARY INFORMATION: St. Lawrence is an intrastate gas distribution system serving residential, commercial, and industrial customers in St. Lawrence County, New York, near the Canadian border. It currently purchases and imports all of its natural gas from Niagara, an affiliated Canadian corporation. Niagara purchases its gas from TransCanada PipeLines Limited. DOE/ERA Opinion and Order No. 33 issued June 22, 1981 (1 ERA 70,532) further amended St. Lawrence's existing import authority granted by the Federal Power Commission on August 8, 1961 (26 FPC 265), to increase the daily volumes from 30,000 Mcf to no more than 43,000 Mcf per day and to increase the annual total from 6.5 Bcf to 9.7 Bcf. On December 3, 1984, DOE/ERA Opinion and Order No. 64 (1 ERA 70,576) granted St. Lawrence authority to import an additional 7,000 Mcf per day of best-efforts gas for a toal of no more than 50,000 Mcf per day during its contract year November 1, 1984 to October 31, 1985.

St. Lawrence here seeks only to extend its authorization to import the additional 7,000 Mcf per day of best-efforts natural gas from November 1, 1985, through its contract year ending October 31, 1987. No other provisions of the existing import authorization are requested to be changed.

The applicant states the requested two-year extension of the current authorized daily maximum would enable it to satisfy fully the demands for all anticipated service loads during the forthcoming contract years. The applicant asserts that the marketability of its gas in relation to alternative fuels in its service area has remained unchanged since its prior application in 1984 and estimates that, if the increased daily volumes are not extended, it may be required to curtail service to interruptible customers during the coming two winter seasons. Such a curtailment of service could cause interruptible customers to shift to imported fuel oil during any such curtailment period and possibly beyond according to St. Lawrence.

On October 7, 1985, Niagara filed with the Canadian National Energy Board to extend its License No. GL–55 to enable it to supply St. Lawrence's additional needs through October 31, 1987.

St. Lawrence supports its application by asserting that the improved marketability of its gas in relation to alternative fuels, primarily imported fuel oil, has demonstrated a need to continue its authorized daily volumes at the present level to fully satisfy all its customer's anticipated demands during the next two years. Further, the applicant states that under its current approved method of monthly volume allocation for the Canadian Volume Related Incentive Price (VRIP) program, the continued availability of the 7,000 Mcf of best-efforts gas can be expected to increase the volumes to which the lower $3.40 per MMBtu price can be applied resulting in greater savings to all classes of its customers over the extended term. The applicant asserts that this could result in an overall lower average unit cost of gas. Finally, St. Lawrence reiterates that its ability under its existing contract to take any daily volume up to the contract maximum without penalty and the absence of any take-or-pay or minimum annual bill obligations provide a competitive import arrangement that is in the public interest and should be extended for the requested two years.

The decision on this application will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest. Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant has asserted that this import arrangement is competitive. Parties opposing the arrangement bear the burden of overcoming this assertion.

Other Information

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate procedural action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR Part 590. They should be filed with the Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Room GA–076, RG–23, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585. They must be filed no later than 4:30 p.m., December 13, 1985.

The Administrator intends to develop a decisional record on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or a trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference should materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, the ERA will provide notice

to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR § 590.316.

A copy of St. Lawrence's application is available for inspection and copying in the Natural Gas Division Docket Room, GA-076, at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on October 28, 1985.

Robert L. Davies,

Acting Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 85-26907 Filed 11-12-85; 8:45 am]

BILLING CODE 6450-01-M

Proposed Consent Order With Empire Gas Corp.

AGENCY: U.S. Department of Energy (DOE); Economic Regulatory Administration (ERA).

ACTION: Notice of Proposed Consent Order and Opportunity for Public Comment.

SUMMARY: The Economic Regulatory Administration (ERA) hereby gives the notice required by 10 CFR 205.199J that it has entered into a Consent Order with Empire Gas Corporation (Empire). The Consent Order resolves the issue of Empire's compliance with the Federal petroleum price and allocation regulations for the period August 19, 1973 through January 27, 1981. This matter was the subject of a Proposed Remedial Order (PRO) Case Number HRO-0250, in which the ERA determined the maximum amount that Empire could have overcharged its customers was $818,412.00. Interest on this amount calculated at full DOE rates would raise the total of the alleged violation to over $1.6 million. In settlement of the allegations contained in the PRO, Empire has agreed to pay the sum of $925,000.00 to DOE. ERA will then initiate a special refund proceeding under 10 CFR Part 205, Subpart V.

As required by § 205.199J, ERA will receive comments on the proposed Consent Order for a period of thirty days following publication of this Notice. All comments received within the thirty day period will be considered before determining whether to issue the proposed Consent Order as a final order of the DOE. Although the Consent Order has been signed by the parties, ERA may, after the expiration of the consent period, withdraw its acceptance of the Consent Order, attempt to obtain a modification of the Consent Order or issue the Consent Order as proposed.

DATE: To be considered, comments must be received by 5:00 pm on the thirtieth day following publication of this Notice.

ADDRESS: Address comments to: Empire Consent Order Comments, Economic Regulatory Administration RG-15, Room 3H-017, U.S. Department of Energy, Washington, D.C. 20585.

FOR FURTHER INFORMATION CONTACT: Leslie Wm. Adams, Assistant Chief Counsel for Administrative Litigation, Economic Regulatory Administration, at the address above, or call (202) 252-4387.

SUPPLEMENTARY INFORMATION: Empire is a reseller of motor gasoline subject to the Federal petroleum price and allocation regulations. During the period covered by this proposed Consent Order (August 19, 1973 through January 27, 1981), Empire engaged in the purchase and resale of refined petroleum products, and was thus subject to applicable price regulations. As a result of an audit conducted by the DOE, the ERA issued a PRO to Empire on August 20, 1984 alleging violations of the Federal petroleum price and allocation regulations during the period May 1978 through February 1979. ERA determined that Empire had not applied the regulations to determine the maximum lawful selling prices for its spot sales of gasoline. Because Empire did not sell gasoline on May 15, 1973, ERA computed its maximum lawful selling prices using the "New Item Rule," 10 CFR 212.111. Based on the findings contained in the PRO, ERA determined that Empire had charged $818,412.00 in excess of the maximum lawful selling prices permitted by applicable DOE regulations during the audit period. Empire subsequently contested these findings of violation.

The major areas of dispute raised by Empire concern the applicability of the price regulations to Empire and whether those regulations were properly applied by the ERA. Specifically, the issues in dispute include: (1) Whether Empire was a "reseller" as that term is defined in the regulations; (2) whether ERA properly applied the new item rule in determining Empire's maximum lawful selling prices; (3) whether Empire was entitled to non-product cost increases in determining maximum lawful selling prices; (4) whether the PRO contains factual errors in matching Empire's purchases and sales; (5) whether the issuance of the PRO to Empire violates agency policy; (6) whether state statutes of limitation bar the enforcement action; and (7) whether the doctrine of laches bars the enforcement action.

While both ERA and Empire believe that it respective legal and factual positions are meritorious, Empire has agreed, without admitting any violation of any DOE regulations, to enter into this Consent Order to avoid complex litigation and disruption of its business. DOE believes the Consent Order is a satisfactory resolution of the compliance matters raised in the PRO concerning Empire's purchases and resale of refined petroleum products. Accordingly, the parties have executed a Consent Order settling all ERA's claims against Empire regarding compliance with the DOE regulations governing refined petroleum products for $925,000.00. The terms and conditions of the Consent Order are as follows:

1. Empire will pay $325,000 to DOE within 10 days of the effective date of this Consent Order, and two payments of $300,000 each, plus interest at the rate of 10.44%, not later than March 1, 1986 and June 1, 1986. The funds will be deposited in escrow for disposition by the DOE.

2. Empire and DOE release each other from further liability for the matters covered by the Consent Order. DOE agrees not to seek penalties.

3. The Consent Order also provides details concerning the confidentiality of the audit data, further recordkeeping, enforcement of the Consent Order and further action in the event of concealment or misrepresentation. The Consent Order does not constitute an admission by Empire or a finding by DOE of a violation of the Federal petroleum price and allocation regulations.

4. Before becoming effective, ERA will receive and consider written comments for a thirty day period following this Federal Register publication. If ERA determines to make the Consent Order final after consideration of public comments, the Consent Order will be a final Order of the DOE to which Empire will have waived its right to judicial or administrative review.

Submission of Written Comments

Interested persons are invited to submit written comments concerning the Consent Order to the address noted above. All comments received by the thirtieth day following publication of this Notice will be considered before determining whether to adopt the Consent Order and issue it as a final order of DOE. Any modifications of the proposed Consent Order which significantly alter its terms or impact will be published for additional comment. If, after considering the comments, ERA determines to issue the Consent Order as a final order, the

Consent Order will be made final and effective by publication of a notice to that effect, describing the action taken, in the **Federal Register.**

Any information submitted in a comment which the writer considers confidential must be identified as such in accordance with the procedures of 10 CFR 205.9(f).

Issued in Washington, D.C., October 30, 1985.

Carl A. Corrallo,

Chief Counsel for Administrative Litigation.

[FR Doc. 85-26925 Filed 11-12-85; 8:45 am]

BILLING CODE 6450-01-M

Office of Hearings and Appeals

Cases Filed; Week of October 11 Through October 18, 1985

During the Week of October 11 through October 18, 1985, the appeals and applications for other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

Dated: November 4, 1985.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of Oct. 11 through Oct. 18, 1985]

Date	Name and location of applicant	Case No	Type of Submission
Oct. 11, 1985	Amoco/Nebraska, Lincoln, NE	RM21-11	Request for Modification/Rescission in the Amoco Second Stage Refund Proceeding. If granted: The November 19, 1985 Decision and Order (Case No. RQ21-65) issued to Nebraska would be modified regarding the State's application for refund submitted in the Amoco second stage refund proceeding.
Oct. 16, 1985	E.D.G., Inc., Washington, DC	KEF-0003	Implementation of Special Refund Procedures. If granted: The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 C.F.R. Part 205, Subpart V in connection with the December 17, 1979 Consent Order entered into with E.D.G., Inc. (formerly Edgington Oil Co.).
Do	Shell Oil Co., Washington, DC	KRD-0002	Motion for Discovery. If granted: Discovery would be granted to Shell Oil Company in connection with the Statement of Objections submitted in response to the Proposed Remedial Order issued to the firm (Case No. HRO-0002).
Do	Union Oil Company of California, Washington, DC	KEF-0004	Implementation of Special Refund Procedures. If granted: The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 C.F.R. Part 205, Subpart V, in connection with the June 13, 1985 Consent Order entered into with Union Oil Company of California.
Do	Windsor Gas Corp., Washington, DC	KEF-0002	Implementation of Special Refund Procedures. If granted: The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 C.F.R. Part 205, Subpart V, in connection with the October 23, 1981, Final Remedial Order issued to Windsor Gas Corporation by the Department of Energy and affirmed by the Federal Energy Regulatory Commission (Docket No. R08Z-17-000).
Do	World Oil Co., Washington, DC	KEF-0005	Implementation of Special Refund Procedures. If granted: The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 C.F.R. Part 205, Subpart V, in connection with the January 19, 1985 Consent Order entered into with World Oil Company.
Oct. 18, 1985	Douglas L. Miller, Washington, DC	KFA-0001	Appeal of an Information Request Denial. If granted: The September 24, 1985, Freedom of Information Request Denial issued by the Director of Personnel would be rescinded and Douglas L. Miller would receive access to certain personnel information regarding DOE vacancy number 85-DP-84.
Do	Placid Oil Co., Washington, DC	KEF-0007	Implementation of Special Refund Procedures. If granted: The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 C.F.R. Part 205, Subpart V, in connection with the February 22, 1984, Consent Order entered into with Placid Oil Company (Case No. 6D0S0005W).
Do	Timco Oil Co., Washington, DC	KEF-0006	Implementation of Special Refund Procedures. If granted: The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 C.F.R. Part 205, Subpart V, in connection with the October 22, 1984, Consent Order entered into with Timco Oil Company.

REFUND APPLICATIONS RECEIVED

[Week of Oct. 11 to Oct. 18, 1985]

Date received	Name of refund proceeding/name of refund applicant	Case No.
10/15/85	Gulf/Hoeffner Service Station.	RF40-3059
10/15/85	L&L/Halliburton Services	RF198-3
10/15/85	Good Hope/Amoco Corp	RF189-8
10/15/85	Harris/Defiance Oil Co	RF193-9
10/15/85	Good Hope/Marathon Petroleum Co.	RF189-11
10/15/85	Good Hope/Tenneco Oil Co.	RF189-10
10/15/85	Good Hope/Ship Service Corporation.	RF189-9
10/15/85	Union Texas/Borg Warner Chemicals.	RF104-8
09/16/85	Field/Amoco Freeway	RF173-11

REFUND APPLICATIONS RECEIVED—Continued

[Week of Oct. 11 to Oct. 18, 1985]

Date received	Name of refund proceeding/name of refund applicant	Case No.
09/16/85	Field/Eastside Amoco	RF173-12
10/15/85	F. O. Fletcher/Williams Heating Oils.	RF172-25
03/04/85	Webco Southern/Airport Fina.	RF202-1
10/11/85	Navajo/Conoco, Inc	RF203-1
10/11/85	Plateau/Conoco, Inc	RF204-1
10/16/85	Wilco/Triangle Gasoline Company of Butler, Inc.	RF115-5
10/16/85	Larco/Kraus Oil Co	RF112-182
10/16/85	Good Hope/Union Texas Petroleum Corp.	RF189-13
10/16/85	Good Hope/System Fuels, Inc.	RF189-12

REFUND APPLICATIONS RECEIVED—Continued

[Week of Oct. 11 to Oct. 18, 1985]

Date received	Name of refund proceeding/name of refund applicant	Case No.
10/16/85	Harris/Priest Petroleum Products.	RF193-10
10/17/85	Good Hope/Consolidated Edison Company of New York, Inc.	RF189-14
10/17/85	Good Hope/Apex Oil Co	RF189-15
10/17/85	Good Hope/Amerada Hess Corp.	RF189-16
10/17/85	Good Hope/Patchogue Oil Terminal.	RF189-17
10/18/85	Gate/Martin Oil Co	RF205-1
10/18/85	Gulf/Yearwood Distributing Co.	RF40-3060

NOTICES OF OBJECTION RECEIVED

[Week of Oct. 11 to Oct. 18, 1985]

Date	Name and location of applicant	Case No.
10/15/85	Red River Oil Co, Moorhead, MN.	HEE-0164
10/17/85	Deiter Bruthers Fuel Company, Inc., Bethlehem, PA.	HEE-0152

[FR Doc. 85-26926 Filed 11-12-85; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. EC86-05-000 et al.]

Baltimore Gas and Electric Co. et al.; Electric Rate and Corporate Regulation Filings

Take notice that the following filings have been made with the Commission:

1. Baltimore Gas and Electric Company

[Docket No. EC86-05-000]

November 1, 1985.

Take notice that on October 23, 1985, Baltimore Gas and Electric Company filed an application with the Federal Energy Regulatory Commission seeking authority, pursuant to Section 204 of the Federal Power Act, to issue not more than $425 million of short-term unsecured promissory notes and commercial paper with a final maturity no later than December 31, 1987.

Comment date: November 22, 1985, in accordance with Standard Paragraph E at the end of this notice.

2. American REF-FUEL Company of Essex County

[Docket No. ER86-73-000]

November 5, 1985.

Take notice that on October 29, 1985 American REF-FUEL Company of Essex County (REF-FUEL) in conjunction with the Port Authority of New York and New Jersey (the Port Authority) tendered for filing proposed FERC Rate Schedule No. 1, appliable to sales of energy by REF-FUEL to Public Service Electric and Gas Company ("PSE&G") from a solid waste refuse-to-energy biomass-fired facility to be located at Newark, New Jersey (the "facility"). The Federal Energy Regulatory Commission ("Commission" or "FERC") has issued an order stating that the Facility is a qualifying small power production facility within the meaning of section 201 of the Public Utility Regulatory Policies Act of 1978.

REF-FUEl requests waiver of the Commission's rule requiring that rate schedule be filed no more than one hundred twenty (120) days prior to the date on which service is to commence under an initial rate schedule. This requirement is intended to prevent the use of stale data in developing the test period for cost-of service-based rates.

Additionally, REF-FUEL seeks waiver of 18 CFR 35.12(b)(5), which requires the submission of cost-of-service and rate design information not relevant in the case of a rate based on the buyer's avoided costs.

Additionally, REF-FUEL seeks waiver of any Commission requirements for filing changes in its Rate Schedule No. 1 in the event of any change in the actual purchase price for energy and capacity calculated pursuant to the formula contained in the Agreement.

In addition to the waivers requested above, REF-FUEL further requests waiver of all Federal Power Act regulatons that the Commission has previously found not to be appropriately applicable to qualifying facilities.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of his notice.

3. Boston Edison Company

[Docket No. ER86-60-000]

November 5, 1985.

Take notice that on October 25, 1985 Boston Edison Company (Edison) tendered for filing Notice of Cancellation of Rate Schedule FERC No. 120. The rate schedule to be cancelled is a power supply contract between the Reading Municipal Light Department an Edison pertaining to the sale of unit power from Edison's New Boston Units 1 and 2. The letter accepting this rate schedule for filing was issued on June 25, 1982 (Docket No. ER82-516). The reason for the cancellation is that the contract has terminated in accordance with its terms. Since the underlying contract is no longer in effect, Edison would request a waiver of notice provisions of 18 CFR 35.15 and would further request that the cancellation become effective on October 25, 1985.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this notice.

4. Boston Edison Company

[Docket No. ER86-61-000]

November 5, 1985.

Take notice that on October 25, 1985, Boston Edison Company (Edison) tendered for filing a notice of filing of Rate Schedule FPC No. 114. The rate schedule to be cancelled is an exchange agreement between Connecticut Light and Power Company and Edison with respect to North Field Mountain and Mystic Unit No. 5. The letter order accepting this rate schedule for filing was issued on April 13, 1977 (Docket No. E-9526). The reason for the cancellation is that the contract has terminated in accordance with its terms. Since the underlying contract is no longer in effect, Edison would request a waiver of notice provisions of 18 CFR § 35.15 and would further request that the cancellation become effective on October 25, 1985.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this notice.

5. Boston Edison Company

[Docket No. ER86-84-000]

November 5, 1985.

Take notice that on October 30, 1985, Boston Edison Company tendered for filing a notice of cancellation of F.P.C. Rate Schedule No. 48 for all requirements service to the Town of Norwood, Massachusetts. Boston Edison Company states that it is cancelling Rate Schedule 48 because the Town of Norwood will begin purchasing 100% of its total electric requirements from New England Power Company as of November 1, 1985. Boston Edison Company requests that the cancellation become effective as of November 1, 1985.

Boston Edison states that it has served a copy of the notice of cancellation upon the Town of Norwood, New England Power Company and the Massachusetts Department of Public Utilities.

Comment date: November 15, 1985, in accordance with Standard Paragraph E at the end of this notice.

Connecticut Light & Power Company

[Docket No. ER86-66-000]

November 5, 1985.

Take notice that on October 28, 1985 Connecticut Light & Power Company tendered for filing Notice of Termination of the following rate schedules:

CL&P's Rate Schedule FERC No. 215
CL&P's Rate Schedule FERC No. 18
CL&P's Rate Schedule FERC No. 131
CL&P's Rate Schedule FERC No. 94
CL&P's Rate Schedule FERC No. 161
CL&P's Rate Schedule FERC No. 85

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this notice.

7. Connecticut Light & Power Company

[Docket No. ER86-74-000]

November 5, 1985.

Take notice that on October 29, 1985, Connecticut Light & Power Company (CL&P) tendered for filing for itself and as successor by merger with the Hartford Electric Light Company

(HELCO) and on behalf of Western Massachusetts Electric Company (WMECO) Notice of Termination of the following rate schedules.

CL&P's Rate Schedule FERC No. 170
CL&P's Rate Schedule FERC No. 172
CL&P's Rate Schedule FERC No. 220

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this notice.

8. Green Mountain Power Corporation

[Docket No. ER86-64-000]

November 5, 1985.

Take notice that Green Mountain Power Corporation (GMP) on October 2, 1985 tendered for filing as a rate schedule an executed agreement dated as of July 30, 1983 between GMP and Connecticut Municipal Electric Energy Cooperative (CMEEC). The proposed rate schedule provides for the sale of non-firm energy by GMP to CMEEC.

GMP states that a copy of the filing was served on CMEEC, as well as the Vermont Public Service Board and Vermont Department of Public Service.

Comment date: November 14, 1985 in accordance with Standard Paragraph E at the end of this notice.

9. Green Mountain Power Corporation

[Docket No. ER86-63-000]

November 5, 1985.

Take notice that Green Mountain Power Corporation (GMP) on October 28, 1985 tendered for filing as a rate schedule an excuted transmission contract dated as of July 1, 1985 between GMP and the Burlington Electric Department ("Burlington"). The proposed rate schedule providies for the use of GMP's transmission facilities to deliver approximately 18MW of Burlington's generation entitlements to Burlington.

GMP states that a copy of the filing was served on Burlington, as well as the Vermont Public Service Board.

Comment date: November 14, 1985 in accordance with Standard Paragraph E at the end of this notice.

10. Duke Power Company.

[Docket No. ER85-644-002]

November 5, 1985.

Take notice that on October 24, 1985, Duke Power Company tendered for filing, pursuant to Commission order issued September 30, 1985 its proposed rate Schedule No. 10 and supporting Cost of Service Statements excluding any EPRI contributions.

Comment date: November 14, 1985 in accordance with Standard Paragraph H at the end of this notice.

11. El Paso Electric Company

[Docket No. ER86-72-000]

November 5, 1985.

Take notice that on October 28, 1985, El Paso Electric Company ("EPE or "the Company") filed revised sheets to rate schedules for the Company's wholesale service to Rio Grande Electric Cooperative ("Rio Grande") at Dell City, texas (FERC No. 18), and Van Horn, Texas (FERC No. 19), to Texas-New Mexico Power Company at Lordsburg, New Mexico (FERC No. 35), and to Imperial Irrigation District (FERC No. 39). The Company has an ownership interest in the Palo Verde No. 1 nuclear unit which began generating power on June 10, 1985. The Company is seeking in this filing to amend its fuel clause in accordance with *Pennsylvania Power & Light Company*, Docket Nos. ER82-493-000 and ER82-494-000, Opinion No. 176, 23 F.E.R.C. ¶61,395 (June 22, 1983), to allow it to calculate fuel costs as if there were no test power being generated except to the extent the facilities generating test power are in the rate base as construction work in progress ("CWIP"). The effect of this treatment and associated accounting is to pass fuel cost savings through to ratepayers over the lives of those facilities than currently through the fuel clause.

The Company requests the Commission to waive the fuel clause regulation (18 C.F.R. § 35.14) and also the 60-day notice requirement to permit this filing to become effective on June 10, 1985, when test generation commenced. The waiver is needed to effectuate the Commission's policy in *Pennsylvania Power & Light*.

Comment date: November 14, 1985 in accordance with Standard Paragraph E at the end of this notice.

12. Green Mountain Power Corporation

[Docket No. ER86-65-000]

November 5, 1985.

Take notice that Green Mountain Power Corporation (GMP) on October 28, 1985 tendered for filing as a rate schedule an executed agreement dated as of December 13, 1983 between GMP and Fitchburg Gas & Electric Light Company (FG&E). The proposed rate schedule provides for the sale of interruptible energy by GMP to FG&E for the period December 13, 1983 through June 30, 1985.

GMP states that a copy of the filing was served on FG&E, as well as the Vermont Public Service Board.

Comment date: November 14, 1985 in accordance with Standard Paragraph E at the end of this notice.

13. Green Mountain Power Corporation

[Docket No. ER86-77-000]

November 5, 1985.

Take notice that Green Mountain Power Corporation (GMP) on October 30, 1985 tendered for filing as a rate schedule an executed agreement dated as of February 9, 1984 between GMP and Central Vermont Public Service Corporation (CVPS). The proposed rate schedule provides for the sale of non-firm energy by GMP to CVPS.

GMP states that a copy of the filing was served on CVPS, as well as the Vermont Public Service Board and Vermont Department of Public Service.

Comment date: November 15, 1985, in accordance with Standard Paragraph E at the end of this document.

14. Indiana & Michigan Electric Power Company

[Docket No. ER86—70-000]

November 5, 1985.

Take notice that American Electric Power Service Corporation (AEP) on October 28, 1985 tendered for filing on behalf of its affiliate Indiana & Michigan Electric Company (I&ME), which is an AEP affiliated operating subsidary, Modification No. 21 dated August 30, 1985 to the Interconnection Agreement dated November 27, 1961 between Illinois Power Company, (Illinois) and I&ME. The Commission has previously designated the 1961 Agreement as I&ME's Rate Schedule FERC No. 23 and Illinois' Rate Schedule FERC No. 9.

Modification No. 21 increased the transmission demand rate for Emergency Energy to 2.75 mills per kilowatthour when I&ME is the supplying party and revises Illinois Emergency demand rate to the rate contained in their current *Rate Schedule for Third Party Purchase and Resale Transactions* on file with the Commission in compliance with FERC order 84 (Order 84 Rate Schedule). In addition, this Agreement revises the provisions for Economy Energy by adding a 3.75 mills per kilowatthour minimum to I&ME's multi-party Economy Energy rate and adds a minimum to Illinois' multi-party Economy Energy rate based upon Illinois' Order 84 Rate Schedule. This Modification also revises the provisions for Non-Displacement Power and Energy by adding a 2.75 Mill per kilowatthour demand charge when I&ME is the supplying party and adds a demand charge based upon Illinois' Order 84 Rate Schedule when Illinois is the supplying party. AEP requests an effective date of October 25, 1985.

I&ME's rates in this Modification are the same as those presently in effect on the AEP system for other AEP affiliated

operating subsidiaries which have previously been submitted and accepted for filing by the Commission. Illinois' rates in this Modification are consistent with the charges associated with the transmission demand rates Illinois presently has in effect for Short Term and Limited Term Service, which are presently on file with the Commission.

Copies of the filing were served upon Illinois Power Company, Public Service Commission of Indiana, and Michigan Public Service Commission.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this notice.

15. Iowa-Illinois Gas and Electric Company

[Docket No. ER86-83-000]

November 5, 1985.

Take notice that Iowa-Illinois Gas and Electric Company (Iowa-Illinois) on its own behalf and as the authorized representative of Iowa Power and Light Company, Iowa Public Service Company and Iowa Southern Utilities Company, on October 30, 1985, tendered for filing three groups of Additional Assignments for Capacity Schedules, all dated October 15, 1985, supplemental to Iowa-Illinois' Rate Schedule FERC No. 39, as supplemented, pursuant to Article IV, and in the form of Exhibit B to, the Operating Agreement/Neal 3 Transmission, dated January 2, 1978 (Operating Agreement), each group of which is proposed to be effective November 1, 1980, June 1, 1981, and October 13, 1983, respectively, as to each of which waivers of the notice requirements are requested by the filing parties in their respective Certificates of Concurrence included in the filing.

It is stated the Additional Assignments, executed by all of the parties to the Operating Agreement (Assignors), for the use and benefit of nonparties (Assignees), reflect mutual accord and will permit the respectively named Assignee to utilize that line segment of Neal 3 Transmission indicated, consistent with the megawatts assigned, as the scheduling path for the Assignee's share of generation, from the unit designated, toward the Assignee's load centers, proposed effective variously as related to events associated with the generation source, *viz.*, effective November 1, 1980, the first of the month following an accredited capacity update and a consequence of a request for additional transmission access from Raun to Lehigh Substations for certain owners of Neal Unit 4 (Algona, Bancroft, Coon Rapids, Corn Belt, Graettinger, Laurens, Milford, Spencer, and Webster City); effective June 1, 1981, the first of the month following accredited capacity update and a consequence of a request for additional transmission access from Sycamore to Lehigh Substations for certain owners of Council Bluffs Unit 3 (Cedar Falls and Corn Belt); and effective October 13, 1983, the date of commercial operation of Louisa Generating Station Unit 1, and a consequence of a request for transmission access from Sycamore to Lehigh Substation for Waverly, an owner of that generation source.

Iowa-Illinois states no new facilities are required to effectuate the Additional Assignments, and that a copy of the filing has been mailed to each of the parties, to each Assignee, to the Iowa State Commerce Commisssion, to the Illinois Commerce Commission, and to the South Dakota Public Utilities Commission.

Comment date: November 15, 1985, in accordance with Standard Paragraph E at the end of this notice.

16. Public Service Company of Indiana, Inc.

[Docket No. EC86-3-000]

November 5, 1985.

Take notice that on October 28, 1985, Public Service Company of Indiana, Inc. (PSI) of Plainfield, Indiana, filed an application pursuant to section 203 of the Federal Power Act seeking an order authorizing Public Service Company of Indiana, Inc. (PSI) to sell certain electrical facilities to Indiana Municipal Power Agency (IMPA) having a value in excess of $50,000.

The electrical facilities proposed to be sold consist of transmission lines, substations and subtransmission facilities used and useful in providing electric service to customers of both PSI and IMPA. The consummation of the sale will not affect electric service to any such customers.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this document.

17. The Connecticut Light and Power Company

[Docket No. ER86-68-000]

November 5, 1985.

Take Notice that on October 28, 1985, The Connecticut Light and Power Company (CL&P) tendered for filing as an initial rate schedule an agreement (the Agreement) between CL&P, Western Massachusetts Electric Company (WMECO, and together with CL&P, the NU Companies) and United Illuminating Company (UI). The Agreement, dated as of April 15, 1985, provides for the UN Companies to sell to UI power from the systems of the NU Companies (system power) that may be available on a daily or weekly basis (a transaction). CL&P states that the timing of transactions cannot be accurately estimated but that the NU Companies would offer to sell such system power to UI only when it was economical to do so. UI would only accept such offer if it was economical to do so.

UI will pay a capacity charge to the NU Companies for each transaction in an amount equal to the megawatts of system capacity reserved for UI by the NU Companies during each hour of a transaction multiplied by the capacity charge rate which is negotiated prior to each transaction. UI will pay an energy charge to the NU Companies for each transaction in an amount equal to the megawatthours delivered by the NU Companies during such transaction multiplied by the energy charge rate. The energy charge rate is based on the heat rate and the replacement fuel price of the generating unit(s) which the NU Companies determine to be available to provide energy at the time of a transaction.

CL&P requests that the Commission waive its customary notice period and allow the Agreement to become effective on April 15, 1985.

WMECO has filed a Certificate of Concurrence in this docket.

The Agreement has been executed by CL&P, WMECO, and by UI (New Haven, Connecticut) and copies have been mailed or delivered to each of them.

CL&P further states that the filing is in accordance with Section 35 of the Commission's Regulations.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this document.

18. The Connecticut Light and Power Company

[Docket No. ER86-85-000]

November 5, 1985.

Take notice that on October 30, 1985, The Connecticut Light and Power Company (CL&P) tendered for filing a proposed rate schedule with respect to a Transmission Agreement date October 1, 1984 between (1) CL&P and Western Massachusetts Electric Company (WMECO) and together with CL&P, the NU Companies) and (2) Commonwealth Electric Company (CEC).

CL&P states that the Transmission Agreement provides for transmission services to CEC for the wheeling of their purchase from the Swift River Company ("SRC") from SRC's hydro electric unit located in Chicopee, Massachusetts during the period from May 1, 1985 to August 31, 2013.

The transmission charge rate is a monthly rate equal to one-twelfth of the estimated annual average cost of transmission service on the electric transmission system of the NU Companies determined in accordance with Appendix A and Exhibits I, II and III thereto, of the Transmission Agreement. The monthly transmission charge is determined by the product of (i) the transmission charge rate ($/kW-month), and (ii) the number of kilowatts CEC is entitled to receive during such month.

CL&P requests that the Commission waives its standard notice period and permit the Transmission Agreement to become effective on May 1, 1985.

WMECO has filed a certificate of concurrence in this docket.

CL&P states that copies of this rate schedule have been mailed or delivered to CL&P, WMECO, and CEC (Wareham, Massachusetts).

CL&P further states that the filing is in accordance with section 35 of the Commission's Regulations.

Comment date: November 15, 1985, in accordance with Standard Paragraph E at the end of this notice.

19. The Dayton Power and Light Company

[Docket No. ER86-71-000]

November 5, 1985.

Take notice that on October 28, 1985 The Dayton Power and Light Company (DP&L) tendered for filing an executed Purchase and Resale Agreement (Agreement) between DP&L and the City of Celina (Celina), Ohio.

The proposed Agreement allows Celina to purchase energy requirements from third parties who will use existing Interconnection Agreement Rate schedules to delivery the energy requirements to DP&L for delivery to Celina.

DP&L requests the Commission waive its notice and filling requirements and permit the proposed Agreement to become effective December 1, 1985.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this notice.

20. The Dayton Power and Light Company

[Docket No. ER86-75-000]

November 5, 1985.

Take notice that on October 29, 1985, The Dayton Power and Light Company (DP&L) tendered for filing an executed Purchase and Resale Agreement (Agreement) between DP&L and the Villae of Waynesfield (Waynesfield), Ohio.

The proposed Agreement allows Waynesfield to purchase energy requirements from third parties who will use existing Interconnection Agreement Rate schedules to delivery the energy requirements to DP&L for delivery to Waynesfield.

DP&L request the Commission waive its notice and filing requirements and permit the proposed Agreement to become effective November 1, 1985.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this document.

21. Washington Water Power Company

[Docket No. ER 86-69-000]

November 5, 1985.

Take notice that on Oct. 28, 1985, The Washington Water Power Company (Washington) tendered for filing a revision to a Transmission Wheeling Tariff, Schedule 62. This tariff is related to transmission wheeling service for borderline customer loads provided only to the Bonneville Power Administration under a currently existing General Transfer Agreement. Revision #1 to Schedule 62 extends the methodology used to calculate charges for borderline transmission wheeling service to United States Bureau of Reclamation loads. The Bureau provides power to the Spokane Indian Tribe at Little Falls, Washington and to the East Greenacres Irrigation District at East Greenacres, Idaho. The revision to Schedule 62 would increase revenues from transmission wheeling service provided to the Bureau by $17,119/year based on the 12-month period ended December 1, 1984. The revision would be effective January 1, 1986.

Washington states that the proposed revison is submitted for the purpose of compensating Washington for increased investment in the transmission system, and for increases in its costs for taxes, capital, operations, and maintenance.

A copy of the filing has been served upon the United States Bureau of Reclamation, the Spokane Indian Tribe, and the East Greenacres Irrigation District.

Comment date: November 14, 1985, in accordance with Standard Paragraph E at the end of this notice.

22. Western Massachusetts Electric Company

[Docket No. ER 86-79-000]

November 5, 1985.

Take notice that on October 30, 1985, Western Massachusetts Electric Company (WMECO) tendered for filing a proposed rate schedule with respect to a Transformation Service Agreement dated December 1, 1984 (Transformation Agreement) between WMECO and Commonwealth Electic Company (CEC).

WMECO states that the Transformation Agreement provides for transformation services to CEC for the delivery of 2,000 kilowatts of CEC's generation entitlement obtained from Swift River Company (SRC) located in Chicopee, Massachusetts during the period from December 1, 1984 to August 31, 2013.

The transformation charge rate is a monthly rate equal to one-twelfth of the estimated annual average cost of transformation service on the WMECO system. The monthly tranformation charge is determined as the product of (i) the transformation charge rate ($/kW-month), and (ii) CEC's total kilowatts of entitlements in the SRC unit.

WMECO requests that the Commission waive its standard notice period and permit the Transformation Agreement to become effective on May 1, 1985.

WMECO states that copies of this rate schedule have been mailed or delivered to CEC (Wareham, Massachusetts).

WMECO further states that the filing is in accordance with Section 35 of the Commission's Regulations.

Comment date: November 15, 1985, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs:

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

H. Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, on or before the comment date. Comments 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. 85-26965 Filed 11-12-85; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPP-180683; FRL-2920-6]

Hawaii Department of Agriculture; Receipt of Application for Emergency Exemption To Use Avermectin B_1; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a request for an emergency exemption from the Hawaii Department of Agriculture (hereafter referred to as the "Applicant") to use the active ingredient avermectin B_1 as an insecticide on 28 acres of ornamental flowers throughout the state. It is the Agency's policy to solicit public comment on applications involving active ingredients which have not been previously registered. Accordingly, EPA is soliciting comment before making a decision whether or not to grant the exemption.

DATE: Comments must be received on or before November 29, 1985.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP-180683" should be submitted by mail to: Information Services Section, Program Manaegment and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., Washington, D.C. 20460. In person, bring comments to: Rm. 236, CM#2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information (CBI)." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for inspection in Rm. 236 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION: By mail: Libby Pemberton, Registration Division (TS-767C), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 716A, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, VA. (703-557-1806).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at his discretion, exempt a State agency from any provisions of FIFRA if he determines that emergency conditions exist which require such exemption.

The Applicant has requested the Administrator to issue a specific exemption to permit the use of the unregistered insecticide, avermectin B_1 (CAS 63AB) on ornamental flowers grown in Hawaii. Information in accordance with 40 CFR Part 166 was submitted as part of this request.

According to the Applicant, there are 25 farms with a total of 28 acres of chrysanthemums, gerbera daisies, snapdragons, and gypsophila grown in greenhouse, shadehouse, and open field in the state of Hawaii. It is stated that the celery leafminer, *Liriomyza trifolii*, was first discovered in Hawaii in 1978. The degree of uncontrollable infestation has increased each year according to the Applicant. The affected crops are sold for their aesthetic qualities. The plants must be free of unsightly mines in order to warrant market price.

The Applicant states that the following are alternative insecticides no longer effective for this use: oxamyl, chlorpyrifos, aldicarb, methyl parathion and permethrin.

The Applicant states that *L. trifoli* was probably introduced from mainland U.S., where *L. trifoli* was already exposed to large doses of organophosphate, carbamate and synthetic pyrethroid insecticides. Presently all registered insecticides must be applied at higher rates and at more frequent intervals which result in minimal control of *L. trifolii*. It is estimated that treatment of affected acreage with Avid 0.15 EC could save Hawaii growers at least $500,000.

The Applicant proposes to treat 28 acres of ornamental flowers throughout Hawaii with Avid 0.15 EC, manufactured by MSD AGVET, a division of Merck & Co., Inc. A maximum of 0.02 pound active ingredient will be applied per acre. Applications will occur throughout the year with no more than 30 pounds of active ingredient to be used.

This notice does not constitute a decision by EPA on the application itself. Use of a chemical under section 18 of FIFRA for which no uses are registered has been determined to be of national interest and therefore, the Agency has decided that public notice and opportunity for public comment pursuant to 40 CFR 166.10 is called for as a part of the informal adjudication for specific exemptions. Accordingly, interested persons may submit written views on this subject to the Program Management and Support Division at the address above. The comments must be received on or before November 29, 1985, and should bear the identifying notation "OPP-180683." All written comments filed pursuant to this notice will be available for public inspection in Rm. 236, Crystal Mall No. 2, at the address given above, from 8:00 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Agency, accordingly, will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by Hawaii.

Dated: October 28, 1985.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 85-26618 Filed 11-12-85; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-210001; FRL 2882-6]

Guidance for Petitioning the Environmental Protection Agency Under Section 21 of the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice provides guidance for preparing citizens' petitions under section 21 of the Toxic Substances Control Act (TSCA). Petitioners' use of this guidance will assist the Environmental Protection Agency to evaluate properly citizens' petitions within the 90-day review mandated by the statute. This guidance will also assist petitioners in effectively presenting their case to EPA with the most pertinent available support.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Environmental Protection Agency, Rm. E-543, 401 M Street, SW., Washington, DC 20460, Toll-free: (800-424-9065), In Washington, DC (554-1404), Outside the USA: (Operator-202-544-1404).

I. Background

Under section 21 of TSCA, any person may petition the Administrator of EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under section 5(e) or 6(b)(2) of TSCA. Within 90 days after a petition has been filed, the Administrator must either grant or deny it. The Administrator may hold a public hearing or may conduct such investigation or proceeding as deemed appropriate in order to determine whether or not the petition should be granted. If the petition is denied, the Administrator must give the reasons for denial in the Federal Register. If granted, the Administrator must promptly initiate an appropriate proceeding in accordance with section 4, 5 6, or 8.

Twenty-seven section 21 petitions have been submitted since 1978, or about three per year. Six of those have been granted, of which five were related to asbestos control.

Within the past 2 years the Agency has received two petitions that set precedents in terms of both the scope of relief requested, and in the amount of EPA resources required to respond. These two petitions, requesting relief for a number of multimedia pollution problems, were submitted with extensive support data. This guidance is intended to help focus future section 21 data submissions directly in support of the petition, thereby eliminating unnecessary efforts by petitioners, and facilitating Agency response.

To understand the requirements of section 21, it is necessary to understand the substance of the four key sections of TSCA under which section 21 relief may be sought, and the criteria which must be met to initiate action under those sections. These factors are discussed in the following sections.

II. Guidance

While the Agency will consider all petitions filed pursuant to section 21 irrespective of adherence to guidance contained herein, petitioners are encouraged to follow these suggestions in order both to present their case effectively and to facilitate the Agency's timely evaluation and response. All items may not be applicable to a specific petition. This guidance is simply intended to serve as a checklist to enable petitioners to present their case as persuasively and comprehensively as possible.

A. General Considerations

1. *Information about the petitioner.* Petitioners should state their name, address, phone number, whom to contact for further information and, if an organization, the nature of its purpose and membership.

2. *Description of the relief requested.* In addition to specifying the TSCA section under which relief is sought (i.e., section 4, 5, 6, and/or 8), petitioners should describe as completely as possible how the action requested would solve the problem. This requirement is discussed in more detail under Unit II Special Considerations, below.

3. *Description of the problem.* In order to take any actions under TSCA sections 4, 5 or 6, EPA must make a finding regarding the potential for or presence of unreasonable risk. This finding must be made not only when a new regulation is issued, but also when an existing regulation is amended or repealed. The term "unreasonable risk" is not defined in the statute, but the legislative history indicates that Congress intended EPA to balance the benefits derived from risk reduction against the social and economic costs incurred, taking into account such factors as the extent and magnitude of risk posed; the societal consequences of removing or restricting use of products; availability and potential hazards of substitutes; and impacts on industry, employment, and international trade. To do this, EPA must have the relevant data. The Agency therefore encourages petitioners to provide as much information as possible in each of the following areas.

(a) *The nature and severity of harm (toxicity) to humans or the environment from the chemicals of concern.* This information indicates a chemical's potential to induce cancer, gene mutations, birth defects, other long-term effects, or such acute effects as neurotoxicity, renal toxicity, hepatotoxicity or irreversible ocular damage. These findings are usually made on the basis of laboratory tests on animals, studies of human populations (epidemiological studies), medical case reports, or by analogy to similar, known toxic chemicals or other relevant studies.

(b) *Exposure.* Exposure data reflect the actual or potential release of a chemical substance to the environment or its actual or potential contact with humans. It may be assessed by qualitative or quantitative estimation of the magnitude, frequency, duration and route (i.e., inhalation, ingestion or skin absorption) of contact. Environmental exposures occur in air, water, soil, or affected ecosystems, and are influenced by such factors as persistence in the environment and bioaccumulation. Exposure assessments are typically based on monitoring data, simulation model estimates, or other measurements. In weighing exposure concerns, the Agency considers such factors as source; concentration levels and duration; populations or media exposed; and whether the scope of the assessment is global, national, regional, local, or site-specific. Exposure assessments are critical to rulemaking. Their purpose is to provide reliable data for risk assessments, which couple exposure and toxicity information. Exposure data are among the most difficult to obtain for both petitioners and the Agency. EPA has proposed guidelines as published in the Federal Register of November 23, 1984, (49 FR 46304) as an aid in carrying out exposure assessments.

(c) *The extent of harm the chemicals of concern present or may present.* This is the risk, which combines the nature and severity of harm (toxicity) with exposure to humans or the environment. This risk may range—in type, severity and immediacy—from thousands of short-term deaths resulting from massive acute exposure to chemicals as a consequence of an industrial disaster, to the longer-range consequences of typically continuous and low level exposure to carcinogens, mutagens, teratogens or other chronic toxicants. Since eventual rulemaking requires defensible assessments of risk based upon the toxicity of the chemical of concern and valid estimates of the extent of exposure, petitioners are encouraged either to (1) submit data that will permit the Agency to conduct a risk assessment, or (2) develop and submit a risk assessment together with the supporting data. The Agency has proposed a series of guidelines (49 FR 46294, Parts VII–X, November 23, 1984) as an aid to carrying out risk assessments for certain toxic effects.

(d) *Risk reduction.* This information indicates possible methods by which risk could be reduced, the degree of risk reduction that could be achieved, the costs of risk reduction methods, and the impacts of any regulation on the economy, small businesses and other affected entities. A basic principle embodied in TSCA is that the Agency must adopt regulatory requirements which impose the smallest social and economic burden possible, commensurate with the level of risk posed by the chemical in question. The Agency urges petitioners to submit any data that might facilitate this analysis.

B. Special Considerations

TSCA requires EPA to make certain findings, before regulating, depending

upon the section of the statute to be used. Accordingly, the Agency's disposition of the petition will depend in large part upon the extent to which the submitted data (1) demonstrate or suggest that EPA will be able to make the relevant findings, and (2) indicate how the requested action would solve the problem. Below is a description of each section, and the findings the Agency must make prior to taking regulatory action.

1. *Rules under section 4.* Section 4 authorizes the Agency to promulgate rules that require manufacturers and/or processors to test specified chemical substances or mixtures in order to evaluate their adverse human or environmental effects. Such testing can be required for chemicals suspected of being harmful or that have substantially large human or environmental exposures. Before requiring manufacturers and processors to conduct tests for health and/or environmental effects, the Agency must find: (1) That the chemical may pose an unreasonable risk of harm to health or the environment, or will be produced in substantial quantities which may result in significant human exposure or environmental release; (2) that insufficient data exist about the effects of the chemical to assess reasonably the impacts of its commercial production; and (3) that testing is needed to develop such data. EPA must also consider the potential economic impacts of mandatory testing before issuing section 4 requirements. In addition to providing data to support these findings, petitioners should explain how the results to be obtained from the requested section 4 test rule will help resolve petitioner's concerns.

2. *Orders under section 5(e).* Section 5(e) authorizes EPA to issue an order prohibiting or limiting the manufacture, processing, distribution in commerce, use or disposal of a new chemical substance when it has determined that existing information is insufficient to evaluate the substance's potential impact. Before issuing such an order, EPA must find (1) that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical, and (2) that the chemical may present an unreasonable risk of injury to health or the environment; or that the chemical will be produced in substantial quantities which may result in significant human exposure or substantial environmental release. Petitioners should provide whatever information is available to support the primary finding and either one or both of the secondary findings, and should indicate how the requested section 5(e) order would provide the desired relief.

3. *Rules under section 6(a).* Section 6(a) authorizes the Agency to impose a range of regulatory controls to prevent the production and use of a chemical substance or mixture from presenting unreasonable risks. Actions taken under section 6(a) must be imposed by rule, and include banning the substance or mixture entirely, prohibiting or limiting certain uses, or requiring labeling or other forms of public notification. To issue a rule under this section, EPA must find that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The key findings relating to unreasonable risk must be made both when a new regulation is proposed, and when an existing regulation is amended or repealed. Petitioners should provide data to support these finds, and describe how the requested section 6 controls would help resolve the problem.

4. *Orders under section 6(b)(2).* Section 6(b)(2) authorizes the Agency to issue an order requiring a description of, and if necessary changes in, a company's quality control procedures in order to identify and remedy inadequacies or defects which cause a chemical substance to present an unreasonable risk to human health or the environment. Before issuing an order requiring a manufacturer or processor to submit a description of his quality control procedures, EPA must have a reasonable basis to conclude that the chemical is produced in a manner which unintentionally causes an unreasonable risk. Petitioners should provide any information bearing on that conclusion.

5. *Rules under section 8.* Section 8 authorizes the Agency, within reasonable bounds, to promulgate rules that require gathering, retaining, and reporting information concerning various factors relating to potential hazards posed by the production and use of chemical substances and mixtures, including the submission of relevant health and safety studies. Petitioners should explain the benefits to be derived from any requested section 8 rule.

C. Action Under Other Statutes

Petitioners are encouraged to consider the risk involved, whether TSCA would most appropriately regulate that risk and, if so, to indicate why TSCA is preferable to other Federal statutes. The Agency emphasizes, here, that section 21 is specific to the particular sections (4, 6, 8, 5(e) and 6(b)) of TSCA enumerated in section 21, and is not appropriate for seeking relief under other sections of TSCA, other laws administered by EPA, or other Federal statutes. Before taking regulatory action under TSCA, EPA determines whether action under a statute or combination of statutes other than TSCA can adequately address the problem. Section 9(a) of TSCA requires EPA to refer unreasonable risks to another agency if EPA determines that such risks may be prevented or sufficiently reduced by action taken under the other agency's law. Section 9(b) requires the Agency to act under one of its other laws unless it is in the public interest to act under TSCA.

Petitioners are particularly encouraged to include a discussion of actions that are being or could be undertaken by State and local authorities to provide the desired relief. Petitioners should describe, for example, any plans that local authorities may have to investigate or regulate the problems identified by petitioners. This discussion should clearly describe why planned or potential State or local actions are or would be inadequate and, to the extent possible, the actions beyond those available under current local authorities that would be necessary to solve the problem. Petitioners should indicate why and how Federal controls would be more effective than State or local controls. Since EPA will review the feasibility of State and local remedies in developing a response to the petition, review will be expedited if petitioners have explored this avenue in advance.

D. Preconsultation

Persons considering filing petitions under section 21 of TSCA are asked first to seek relief, if appropriate, from local and State officials. Failing successful resolution at those levels, petitioners are encouraged, because of the effort required to marshal all relevant information and arguments, to consult with the Agency prior to filing a petition formally. This will enable petitioners to determine what information the Agency already has on the problem, what action it has taken or is taking, what particular information the Agency may need to make its decision, and what alternatives to Federal regulation may exist. Such preconsultations could result not only in strengthening the support documentation for petitions but, in some cases, in immediate resolution of petitioners' concerns.

E. EPA Decisions on Petitions

Experience has shown that the Agency cannot always provide the relief sought by petitioners. The Agency must address each petition in terms of (1) magnitude of risk, (2) risk reduction achievable relative to cost, and (3) both of the above relative to existing regulatory priorities. Petitioners should, insofar as possible, provide data to support their contention that EPA should modify its existing regulatory agenda to accommodate their request. Although TSCA authorizes EPA to impose regulations applicable to specific geographical areas, petitioners requesting area-specific rules are encouraged to demonstrate the benefits to be derived relative to rules focused on the national level, or the possible implications of the proposed area-specific rule for future regulation on a national level.

For further assistance in preparing and submitting citizens' petitions, prospective petitioners should contact the designated Toxic Substances Coordinator at any of the 10 EPA Regional Offices as follows:

Regional Offices

EPA, Region I, JFK Building, Room 2203, Boston, MA 02203, (617–223–7210);
EPA, Region II, 26 Federal Plaza, Room 900, New York, NY 10278, (212–264–2525);
EPA, Region III, 841 Chestnut Street, Philadelphia, PA 19107, (215–597–9800);
EPA, Region IV, 345 Courtland Street, N.E., Atlanta, GA 30365, (404–881–4727);
EPA, Region V, 230 South Dearborn Street, Chicago, IL 60604, (312–353–2000);
EPA, Region VI, 1201 Elm Street, Dallas, TX 75270, (214–767–2600);
EPA, Region VII, 726 Minnesota Avenue, Kansas City, KS 66101, (913–236–2800);
EPA, Region VIII, One Denver Place, 999–18th St.—Suite 1300, Denver, CO 80202–2413, (303–293–1603).
EPA, Region IX, 215 Fremont Street, San Francisco, CA 94105, (415–974–8153);
EPA, Region X, 1200 Sixth Avenue, Seattle, WA 98101, (206–442–5810).

III. Conclusion

The guidance contained in this notice will help petitioners under section 21 of TSCA present their concerns to EPA with the maximum amount of relevant documentation, and will help expedite the Agency's evaluation within the 90-day review period.

Dated: November 1, 1985.

Lee M. Thomas,

Administrator.

[FR Doc. 85–26938 Filed 11–12–85; 8:45 am]
BILLING CODE 6560–50–M

[OW–10–FRL 2922–8]

Petition Requesting Sole Source Aquifer Designation of the North Florence Dunal Aquifer, Lane County, OR, and Request for Public Comment

AGENCY: Environmental Protection Agency.

ACTION: Public Comments Requested.

SUMMARY: The Environmental Protection Agency, Region 10, invites public comment on a petition requesting designation of the North Florence Dunal Aquifer in western Lane County, Oregon. In particular, EPA requests data and references to additional sources of information. If the aquifer is so designated, no commitment for federal financial assistance may be entered into for any project which EPA determines may contaminate the aquifer so as to create a significant hazard to public health. EPA will hold one or more informal public meetings at locations and dates to be announced later.

DATE: Comments must be submitted on or before December 30, 1985.

ADDRESSES: Comments should be addressed to Wendy Marshall, Environmental Protection Agency, Region 10, Drinking Water Programs Branch, M/S 409, 1200 Sixth Avenue, Seattle, Washington 98101.

The petition and related documents can be examined during normal business hours at the following locations:

Environmental Protection Agency, Region 10 Library—12th Floor, 1200 Sixth Avenue, Seattle, Washington 98101
Environmental Protection Agency, Oregon Operations Office, 522 Southwest Fifth Avenue, Yeon Building, 2nd Floor, Portland, Oregon 97204
Florence Public Library, 250 Highway 101 North, Florence, Oregon 97439

FOR FURTHER INFORMATION CONTACT: Wendy Marshall at (206) 442–1890 or FTS 399–1890.

SUPPLEMENTARY INFORMATION: On June 2, 1985, Shirlee J. Gardinier, of Florence, Oregon, submitted a petition to the Administrator of the Environmental Protection Agency (EPA) requesting that the North Florence Dunal Aquifer, located in Lane County, Oregon, be designated a sole source aquifer. Additional technical information was provided to EPA on July 30, 1985.

Information on Petitioned Area

The North Florence Dunal Aquifer underlies an area in Lane County, Oregon, that is bounded by the Siuslaw River to the south, the Pacific Ocean to the west, Sutton Creek to the north and an extensive bedrock ridge east of Collar, Clear, and Munsel Lakes to the east. The dune sands in the areas, which overlie a basement rock of coherent sandstone and siltstone, form the North Florence Dunal Aquifer. The northern Florence dune area is characterized by a low, undulating surface that slopes gently upward from the sea to the base of the bedrock ridges that form the eastern boundary of the dune sheet.

Approximately 8,000 people live in the North Florence area. There are two public water systems serving the area. The Heceta Water District serves approximately 3,250 people from an intake in Clear Lake, an aquifer fed lake, with chlorination as the only treatment. The City of Florence water system serves approximately 4,500 people. The city's two wells are located on the east side of the city in a sand dune area. Treatment is provided at a plant near the wells where the supply is chlorinated and treated to precipitate iron. The Heceta Water District provides additional water to the City of Florence during the summer months. Those persons not served by either water system utilize private wells for their source of water.

Rainfall, which is the only source of recharge to the aquifer, varies across the width of the aquifer with an estimated 65 inches at the beach line to 80 inches or more at the crest of the ridge on the eastern boundary. Most of the rainfall soaks into the sand and becomes recharge to the ground water. The high permeability of the sand is demonstrated by the lack of streams originating in the dunes area in spite of over five feet of rainfall annually.

After rainfall percolates to the water table, the water begins to move through the aquifer toward a discharge point. Most of the water is discharged directly to the ocean, to the Siuslaw River or to Sutton Creek. A portion of the water from the upper reaches of the aquifer flows to Collard, Clear, Ackerly or Munsel Lakes. From there it either flows out the Munsel Creek system, if pumped out by the Heceta Water District, or reenters the ground-water system at the southern end of these lakes.

The quality of the ground water in the North Florence Dunal Aquifer is generally very good. Most chemical

constituents are in very low concentrations due to the relatively inert quality of the fresh sands, and the high flushing rates from heavy rainfall and rapid ground-water turnover although an iron problem exists because of iron mobilization by organic acids. Subsurface sewage disposal (outside the Florence which is sewered), industrial waste, storm runoff, or other activities related to human habitation on the surfaces of such a porous aquifer could, however cause degradation of ground-water quality throughout the aquifer.

Coastal lakes south of the Siuslaw River or possibly some minor streams north of the Heceta Water District could, perhaps, provide alternative sources of drinking water to the area should aquifer contamination occur. These lakes and streams, however, are of lower quality and would require more expensive treatment and longer transmission to the service area, thus making them inappropriate as alternative sources.

Consequences of Designation

Section 1424(e) of the Safe Drinking Water Act states; "If the Administrator determines, on his own inititative or upon petition, that an area has an aquifer which is the sole or principal drinking water source for the area and which, if contaminated, would create a significant hazard to public health, he shall publish notice of that determination in the Federal Register. After the publication of any such notice, no commitment for Federal financial assistance (through a grant, contract, loan guarantee, or otherwise) may be entered into for any project which the Administrator determines may contaminate such aquifer through a recharge zone so as to create a significant hazard to public health, but a commitment for Federal financial assistance may, if authorized under another provision of law, be entered into to plan or design the project to assure that it will not so contaminate the aquifer."

Public Meetings

EPA will hold informal public meeting to explain the sole source aquifer program and provide the opportunity for public comment. The Regional Administrator will give widespread notice of such meetings.

Dated: October 18, 1985.

Ernesta B. Barnes,

Regional Administrator

[FR Doc. 85-26935 Filed 11-12-85; 8:45 am]

BILLING CODE 6560-50-M

[SAB-FRL-2922-9]

Science Advisory Board, Environmental Engineering Committee; Open Meeting

Under Pub. L. 92-463, notice is hereby given that a one-day meeting of a Subcommittee of the Environmental Engineering Committee of the Science Advisory Board will be held at the Environmental Protection Agency, Conference Room #3 North (on the Ground Floor, near the EPA Washington Information Center), Waterside Mall, 401 M Street S.W., Washington, DC on December 3, 1985. The meeting will begin at 10:00 a.m. and last until 5:00 p.m.

The purpose of the meeting will be to begin detailed technical review of guidance for the establishment of Alternate Concentration Limits for releases from RCRA-permitted hazardous waste disposal facilities, and to review two case studies prepared by the Office of Solid Waste.

The meeting is open to the public. Any member of the public wishing to participate or obtain further information about the meeting should contact Harry C. Torno, Executive Secretary, at (202) 382-2552, or Terry F. Yosie, Director, Science Advisory Board, at (202) 382-4126. Public comments will be accepted at the meeting. Written comments will be accepted in any form, and there will be opportunity for brief oral statements. Anyone wishing to make oral or written comments must contact Mr. Torno prior to November 26, 1985, in order to be placed on the agenda.

Any member of the public wishing to attend should contact Mrs. Brenda Browne at (202) 382-2552.

Dated: November 4, 1985.

Terry F. Yosie,

Director, Science Advisory Board.

[FR Doc. 85-26934 Filed 11-12-85; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL HOME LOAN BANK BOARD

Community Reinvestment Act; Agency Information Collection Activities Under OMB Review

Dated: November 6, 1985.

AGENCY: Federal Home Loan Bank Board.

ACTION: Notice.

SUMMARY: The public is advised that the Federal Home Loan Bank Board has submitted a request for extension, without revision, of its information collection, "Community Reinvestment Act" to the Office of Management and Budget for approval in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35).

COMMENTS: Comments on the information collection request are welcome and should be submitted within 15 days of publication of this notice in the Federal Register. Comments regarding the paperwork-burden aspects of the request should be directed to: Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, D.C. 20503, Attention: Desk Officer for the Federal Home Loan Bank Board.

The Board would appreciate commenters sending copies of their comments to the Board.

Requests for copies of the proposed information collection request and supporting documentation are obtainable at the Board address given below:

Director, Information Services Section, Office of Secretariat, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, Phone: 202-377-6933.

FOR FURTHER INFORMATION CONTACT: Gilda Morse, Office of Community Investment. Telephone: (202) 377-6822.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 85-26962 Filed 11-12-85; 8:45 am]

BILLING CODE 6720-01-M

Securities Offerings; Agency Information Collection Activities Under OMB Review

Dated: November 6, 1985.

AGENCY: Federal Home Loan Bank Board.

ACTION: Notice.

SUMMARY: The Public is advised that the Federal Home Loan Bank Board has submitted a request for a new information collection, "Securities Offerings" to the Office of Management and Budget for approval in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Comments: Comments on the information collection request are welcome and should be submitted within 15 days of publication of this notice in the Federal Register. Comments regarding the paperwork-burden aspects of the request should be directed to: Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, Attention: Desk Officer for the Federal Home Loan Bank Board.

The Board would appreciate commenters sending copies of their comments to the Board.

Requests for copies of the proposed information collection request and supporting documentation are obtainable at the Board address given below:

Director, Information Services Section, Office of Secretariat, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, Phone: 202–377–6933.

FOR FURTHER INFORMATION CONTACT: John P. Harootunian, Office of the General Counsel. Phone: (202) 377–6416.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 85–26963 Filed 11–12–85; 8:45 am]

BILLING CODE 6720–01–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act, 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to communicate with the Director, Bureau of Tariffs, Federal Maritime Commission, Washington, DC 20573.

George S. Engers dba G.S. Engers & Company, 141 Penn Street, El Segundo, CA 90245

By the Federal Maritime Commission.

Bruce A. Dombrowski,

Acting Secretary.

Dated: November 6, 1985.

[FR Doc. 85–26964 Filed 11–12–85; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

First Colonial Bankshares Corp.; Correction

This notice corrects a previous **Federal Register** document (FR Doc. No. 85–25306), published at page 43004 of the issue for Wednesday, October 23, 1985.

First Colonial Bankshares Corporation, Chicago, Illinois; to acquire 100 percent of the voting shares of both All American Bank of Chicago, Chicago, Illinois and Northwest Commerce Bank, Rosemont, Illinois.

Board of Governors of the Federal Reserve System, November 6, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85–26909 Filed 11–12–85; 8:45 am]

BILLING CODE 6210–01–M

First Commerce Corp.; Correction

This notice corrects a previous **Federal Register** document (FR Doc. No. 85–26274), published at page 45871 of the issue for Monday, November 4, 1985.

The correct name of the subsidiary company is First Commerce Investment Services, Inc.

Board of Governors of the Federal Reserve System, November 6, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85–26910 filed 11–12–85; 8:45 am]

BILLING CODE 6210–01–M

Marine Midland Banks, Inc., the Hong Kong and Shanghai Banking Corp., Kellett N.V., and HSBC Holdings B.V.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23 (a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23 (a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than December 2, 1985.

A. **Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Marine Midland Banks, Inc.*, Buffalo, New York; *The HongKong and Shanghai Banking Corporation*, Hong Kong, B.C.C.; *Kellett N.V.*, Curacao, Netherlands Antilles; and *HSBC Holdings B.V.*, Amsterdam, The Netherlands; to acquire Commercial Credit Business Loans, Inc., Baltimore, Maryland; Commercial Credit Business Loans, Inc., Los Angeles, California; and Commercial Credit Business Loans, Inc., New York, New York; and thereby engage in commercial finance lending activities pursuant to § 225.25(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, November 6, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85–26911 Filed 11–12–85; 8:45 am]

BILLING CODE 6210–01–M

The Peoples Bancshares Corp., et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically

any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 2, 1985.

A. Federal Reserve Bank of Cleveland (Lee S. Adams, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *The Peoples Bancshares Corporation,* Van Wert, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of The Peoples Bank and Trust Company, Van Wert, Ohio.

B. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Reliance Bank Holding Company,* Atlanta, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Reliance Bank and Trust Company, Atlanta, Georgia, which has applied for membership in the Federal Reserve System and presently operates as Reliance Trust Company, Atlanta, Georgia, and Reliance Credit Union, Atlanta, Georgia. Comments on this application must be received not later than November 29, 1985.

C. Federal Reserve Bank of Minneapolis (Bruce J. Hedblom, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Security Bank Shares, Inc.,* Port Wing, Wisconsin; to acquire 90.7 percent of the voting shares of Bank of New Auburn, New Auburn, Wisconsin.

D. Federal Reserve Bank of Dallas (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Central Texas Bancshares, Inc.,* Austin, Texas; to become a bank holding company by acquiring 80 percent of the voting shares of Guaranty National Bank, Austin, Texas.

2. *T N Bancshares, Inc.,* El Paso, Texas, to acquire 92.70 percent of the voting shares of Coronado Bancshares, Inc., El Paso, Texas, thereby indirectly acquiring Coronado Bank, El Paso, Texas.

Board of Governors of the Federal Reserve System, November 6, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-26912 Filed 11-12-85; 8:45 am]

BILLING CODE 6210-01-M

Swiss Bank Corp., et al.; Applications To Engage de Novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo,* either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 27, 1985.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Swiss Bank Corporation,* Basle, Switzerland; to engage *de novo* through its subsidiary, Basle Asset Holding Corporation, New York, New York, in making or acquiring secured and unsecured loans and other extensions of credit, and holding or taking title to collateral in connection therewith, pursuant to § 225.25(b)(1) of Regulation Y.

B. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. *Keystone Heritage Group Incorporated,* Lebanon, Pennsylvania; to engage *de novo* through its subsidiary, Keystone Heritage Life Insurance Company, Phoenix, Arizona, in credit life, accident and health underwriting, as reinsurer, in connection with extensions of credit made by Applicant's subsidiary bank, Lebanon Valley National Bank, Lebanon, Pennsylvania, pursuant to § 225.25(b)(9) of Regulation Y. These activities would be conducted in Lebanon, Schuylkill, Berks, Dauphin and Lancaster Counties of central Pennsylvania. Comments on this application must be received not later than November 29, 1985.

2. *Peoples National Bancorp, Inc.,* State College, Pennsylvania; to engage through its subsidiary, Central Pennsylvania Life Insurance Company, Phoenix, Arizona, in credit life, accident and health underwriting, as reinsurer, in connection with extensions of credit made by Applicant's subsidiary bank, Peoples National Bank of Central Pennsylvania, State College, Pennsylvania, pursuant to § 225.25(b)(9) of Regulation Y. These activities would be conducted in central Pennsylvania.

Board of Governors of the Federal Reserve System, November 6, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-26913 Filed 11-12-85; 8:45 am]

BILLING CODE 6210-01-M

Wells Fargo & Co., San Francisco, CA; Proposal To Engage in Municipal Securities Placement Advisory Activities

Wells Fargo & Company, San Francisco, California, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) ("Act") and § 225.23(a)(3) of the Board's Regulation Y (12 CFR 225.23(a)(3)), to act as advisor in connection with the private placement of municipal debt securities with institutional and other sophisticated investors. These securities include municipal revenue bonds, which banks are prohibited from selling or underwriting under the Glass-Steagall Act.

Applicant would engage in the proposed activity indirectly through Wells Fargo Municipal Securities Corporation, also of San Francisco ("Company"), a wholly-owned subsidiary of Applicant's direct subsidiary, Wells Fargo Capital Markets Inc., which provides leasing, fixed-rate

financing, asset-based financing, and other types of credit facilities requiring specialized financial skills. The customers to be served would be either municipalities seeking to raise funds for a project through the issuance of securities or commercial enterprises seeking municipal revenue bond financing. Company would conduct the activity from an office in San Francisco and would serve customers throughout the United States and abroad.

Under this proposal, Company would provide advice to customers concerning the structure of the financing, including timing, interest rates, maturity, and the terms and conditions that are likely to be required by purchasers. In addition, Company would assist in the preparation of private placement memoranda, identification of and initial contact with potential investors, arrangement of meetings between customers and potential investors, and negotiations between custoemrs and purchasers. Applicant states that the purchasers of securities placed with the assistance of Company would be sophisticated investors, and the minimum purchase by any single investor would be over $1 million. Company would not make any commitment to sell or to use best efforts to sell municipal securities in any specific amount, but would act solely as a financial advisor, receiving compensation in the form of a fixed fee or a percentage of the proceeds of the issuance.

Section 4(c)(8) of the Bank Holding Company Act provides that a bank holding company may, with Board approval, engage in any activity "which the Board after due notice and opportunity for hearing has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto." The Board has not previously approved the proposed activity for bank holding companies. Applicant states that the activities are so closely related to banking or managing or controlling banks as to be a proper incident thereto on the basis that banks for a number of years have engaged in private placement advisory services of the type Applicant proposes. Applicant states the approval of the activity for bank holding companies would result in benefits to the public in the form of increased competition, gains in convenience and efficiency, and lowered costs and easier access to information. In addition, Applicant states that banks' conduct of the activity has not resulted in adverse effects.

The Glass-Steagall Act restricts the third party securities activities of banks and affiliates of banks. Section 20 of that Act (12 U.S.C. 377) prohibits affiliates of banks from being "engaged principally in the issue, flotation, underwriting, public sale, or distribution" of securities. In Applicant's opinion, it would not be engaged in such activities because it would act solely as agent-advisor for the customer and would not be involved in a public distribution of securities. The Board recently ruled that private placement activities with respect to commercial paper securities conducted by Bankers Trust Company, a state member bank, would not violate sections 16 and 21 of the Glass-Steagall Act (12 U.S.C. 24 Seventh) on those bases. *Statement Concerning Applicability of the Glass-Steagall Act to the Commercial Paper Placement Activities of Bankers Trust Company* (Press Release dated June 4, 1985). In approving the commercial paper placement activity of Bankers Trust, the Board noted that any extensions of credit to issuers would not be related in time or purpose so as to support the issuer's commercial paper activities, and the Board stated its analysis was premised on the assumption that the bank would not provide its letter of credit to support a particular issue of commercial paper placed by the bank.

Applicant states that advances of credit by the bank to Company's customers would be made at different times, for different purposes and under different terms than the securities placed with Company's assistance. However, Company states it might occasionally provide private placement advisory services in connection with an issue of industrial revenue bonds that is supported by a letter of credit issued by its affiliate, Wells Fargo Bank, N.A.

Applicant argues that the simultaneous provision of placement services by Company and letter of credit services to the same customers by its banking subsidiary would not violate the Glass-Steagall Act because each service would be provided by a separate entity. Applicant also maintains that section 20 of the Act does not necessarily prohibit a bank holding company affiliate from providing both credit assistance and placement service to issuers. Applicant's argument is based on differences in the terms of section 20, which restricts the "public sale" of securities by affiliates of banks, and the terms of sections 16 and 21, which restrict the "selling" of securities by banks. In addition, Applicant states that any letter of credit would be issued only after the bank's independent credit review and prior to Company's agreeing to act as placement advisor, which in the Applicant's view would eliminate the possibility of hazards, including conflicts of interest, that prompted Congress to enact the Glass-Steagall Act.

Interested persons may express their views on whether the proposed activity (1) is permissible under the Glass-Steagall Act and (2) is "so closely related to banking or managing or controlling banks as to be a proper incident thereto," including whether the proposal as a whole can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on these questions must, as required by section 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of the reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of San Francisco.

Any views or requests for hearing should be submitted in writing to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551, no later than December 6, 1985.

Board of Governors of the Federal Reserve System, November 6, 1985.

William W. Wiles,

Secretary of the Board.

[FR Doc. 85-26914 Filed 11-12-85; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 85N-0475]

Dietary Characteristics and Cancer; Announcement of Study and Request for Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB) is undertaking a study on dietary characteristics and cancer. FASEB is inviting submission of scientific data and information on certain specific questions related to this subject for consideration by the Scientific Stering Group. The Scientific Stering Group will provide an opportunity for the presentation of written and oral views, information, and data on dietary characteristics and cancer at an open meeting in March 1986. The date and location of the meeting will be announced in the **Federal Register** at a later date.

DATES: Written scientific data, information, and related reference materials on dietary characteristics and cancer must be received by February 28, 1986. Requests to make oral presentations at the open meeting must be in writing, be postmarked before February 28, 1986, and be received by March 7, 1986.

ADDRESSES: Written scientific data, information, and related reference materials should be submitted as follows: Two copies to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fisher Lane Rockville, MD 20857; and two copies to K.D. Fisher, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville, Pike, Bethesda, MD 20814. Written requests to make oral presentations should be directed in the same manner to both addresses above.

FOR FURTHER INFORMATION CONTACT: K.D. Fisher, Life Sciences Research Office (address above), 301–530–7030.

SUPPLEMENTARY INFORMATION: FDA is announcing that FASEB, under its contract with FDA (No. 223–83–2020), will study the available information on dietary characteristics and cancer. In response to FDA's request that FASEB study this matter, the Scientific Steering Group that FASEB established under the contract recommended that the Life Sciences Research Office perform this task by reviewing information and data being generated by a major study that is assessing the effects of certain dietary constituents on cancer mortality in the People's Republic of China. This study is being conducted by Cornell University and the Chinese Center for Preventive Medicine. Because of the unique nature of the data from this study and of the scientific expertise available both at Cornell University and the Institute of Health in Beijing, People's Republic of China, study represents a rare opportunity to obtain information, data, and views on issues associated with diet, nutrition, and cancer. The insights of the scientists involved in the study and the results of their investigations will be explored by the Life Sciences Research Office and the Scientific Steering Group.

The Life Sciences Research Office and the Scientific Steering Group will examine the information developed by this major project on the following matters: (1) The extent to which epidemiological data on cancer mortality derived from the China study correlate with currently available information on diet and nutrition. (2) Whether dietary levels of vitamins A, C, and E affect cancer mortality rates among subsets of the population that are differentiated by the levels of these nutrients in their diets. (3) Whether dietary intake levels of selenium and other trace elements affect cancer mortality rates among subsets of the population that are differentiated by the levels of these nutrients in their diets. (4) Whether dietary intake levels of lipids (fat and cholesterol) affect cancer mortality rates among subsets of the population that are differentiated by the levels of these nutrients in their diets. FASEB will also consider whether it is possible to determine the composition of the fat (i.e., saturated and polyunsaturated) in the diet from the available data. (5) Whether dietary caloric level and content of dietary fiber affect cancer mortality rates among subsets of the population that are differentiated by the levels of calories and dietary fiber in their diets. (FASEB will also explore what is known about the effects of the various forms of fiber.) (6) Whether some food preservation and preparation methods alter cancer mortality.

A list of the members of the Scientific Steering Group may be obtained by writing to the contact person (address above).

In accordance with 21 CFR 14.15(b)(1), notice is given that the Scientific Steering Group will hold an open meeting in March 1986, during which an opportunity will be provided for the public to present written and oral views, information, and data on dietary characteristics and cancer. The exact date and location of the open meeting will be announced in the **Federal Register** at a later date.

This notice invites submission of scientific data and information on dietary characteristics and cancer for consideration by the Scientific Steering Group. Two copies of any data and information should be submitted to FDA's Dockets Management Branch (address above). The deadline for receipt of such information is February 28, 1986. Written requests to make oral presentations at the open meeting should be sent to the addresses above, must be postmarked before February 28, 1986, and be received by March 7, 1986.

Dated: November 6, 1985.

Mervin H. Shumate,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85–26905 Filed 11–12–85; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 85F–0491]

Ferro Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ferro Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2,4-di-*t*-butylphenyl 3,5-di-*t*-butyl-4-hydroxybenzoate as a light stabilizer for polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5B3895) has been filed by Ferro Corp., 7050 Krick Rd., Bedford, OH 44146, proposing that § 178.2010 *Antioxidants and/or stabilizers for polmers* (21 CFR 178.2010) be amended to provide for the safe use of 2,4,di-*t*-butylphenyl 3,5-di-*t*- butyl-4-hydroxybenzoate as a light stabilizer for polymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: November 1, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-26903 Filed 11-12-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85F-0477]

INI Agrico, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that INI Agrico, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a source of gamma radiation to control insect infestation and to inhibit growth and maturation in fresh papaya at doses not to exceed 100 kilorad (krad).

FOR FURTHER INFORMATION CONTACT: Clyde A. Takeguchi, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC. 20204, (202) 472-5740.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5M3882) has been filed by INI Agrico, Inc., 100 Elwell Ct., Suite 232, Palo Alto, CA 94303, proposing that Part 179 (21 CFR Part 179) be amended to provide for the safe use of a source of gamma radiation to control insect infestation and to inhibit growth and maturation in fresh papaya at doses not to exceed 100 krad.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: November 1, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-26902 Filed 11-12-85; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending an advisory committee meeting notice of the Blood Products Advisory Committee to reflect a change in the agenda for the open committee discussion, notice of which was published in the **Federal Register** of October 18, 1985 (50 FR 42225). The agenda for the open committee discussion is revised to read as follows:

"*Open committee discussion.* On November 21, the committee will discuss (1) safety and effectiveness data for the use of anti-lymphocyte globulin in human organ transplantation and (2) an update on recent developments on Human T-Lymphotropic Virus Type III (HTLV-III) tests and related issues. On November 22, the committee will (1) discuss the reclassification of category IIIA products, Whole Blood (Human) Heparin, and Fibrinolysin (Human), License Number 2, Merck Sharp and Dohme, Division of Merck and Co., Inc., under the provisions of 21 CFR 601.26; (2) consider increasing the permitted 6-hour interval to 8 hours between collection of whole blood and separation of platelets and plasma; and (3) discuss safety and effectiveness data for a new medical device (plasma/cell separator)."

FOR FURTHER INFORMATION CONTACT: Isaac F. Roubein, Center for Drugs and Biologics (HFN-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4696.

Dated: November 6, 1985.

Mervin H. Shumate,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-26904 Filed 11-12-85; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

Recombinant DNA Research; Action Under Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of action under NIH Guidelines for Research Involving Recombinant DNA Molecules.

SUMMARY: This notice sets forth an action taken by the Director, NIH, under the November 1984 NIH Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266).

EFFECTIVE DATE: November 13, 1985.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Dr. William J. Gartland, Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20892 (301) 496-6051.

SUPPLEMENTARY INFORMATION: Today an action is being promulgated under the NIH Guidelines for Research Involving Recombinant DNA Molecules. In accordance with Section IV-C-1-b of the NIH Guidelines, this action has been found to comply with the NIH Guidelines and to present no significant risk to health or the environment.

I. Approval to Field-Test Disease Resistant Tobacco Plants

In a submission dated May 5, 1983, Dr. Winston Brill of Cetus Madison Corporation (CMC) requested approval under Appendix L of the NIH Guidelines for Research Involving Recombinant DNA Molecules to field test plants grown from seeds containing recombinant DNA. CMC and its successor, Agracetus, do not receive any support for recombinant DNA research from the NIH and, therefore, are not required to comply with the NIH Guidelines. All submissions by CMC were made voluntarily under Part VI of the NIH Guidelines. A review by the Plant Working Group of the NIH Recombinant DNA Advisory Committee (RAC) concluded that the submission did not meet the criteria required for approval under Appendix L of the NIH Guidelines and would, therefore, require review not only by the RAC Plant Working Group but also by the full RAC.

On July 1, 1983, CMC submitted a revised proposal to field test plants grown from seeds containing recombinant DNA. After review by the Plant Working Group, additional information was requested.

On August 19, 1983, CMC submitted a revised proposal to field test plants engineered by recombinant DNA techniques. The proposal was reviewed by the RAC Plant Working Group on September 7, 1983, and by the full RAC on Septebmer 19, 1983. At its September 19, 1983 meeting, the RAC passed a motion by a vote of 12 in favor and 1 opposed. The motion stated that while the proposal was acceptable in principle, it required further amplification and clarification before approval.

On October 21, 1983, Dr. Brill provided further data on the field design and the types of observations to be made and

also limited the request to tobacco plants.

On December 21, 1983, the RAC Plant Working Group unanimously recommended approval of the request as described in the submissions from CMC of August 19, 1983, and October 21, 1983.

On January 24, 1984, the U.S. Department of Agriculture (USDA) Recombinant DNA Committee unanimously concurred with the recommendation of the NIH RAC Plant Working Group.

The proposal was reviewed by the RAC at its June 1, 1984, meeting. The RAC with no negative votes recommended approval of the proposal.

On August 30, 1984, NIH was informed that the business of CMC had been transferred to a partnership having the name "Agracetus."

On September 14, 1983, a lawsuit was filed (Foundation on Economic Trends, et al. v. Margaret Heckler et al., Civil Action #83-2714 in the United States District Court for the District of Columbia). On May 16, 1984, Judge John Sirica issued a preliminary injunction in this case. The injunction was partly affirmed and partly vacated by the Appeals Court in a decision of February 27, 1985. Although the preliminary injunction specifically does not apply to proposals voluntarily submitted to the NIH (as is the case with the Agracetus proposal), I requested that an Environmental Assessment be prepared prior to my approval of this proposal. I signed an Environmental assessment and Finding of No Significant Impact on August 14, 1985.

Both the material submitted by Agracetus and the Environmental Assessment contain material identified by Agracetus as proprietary information.

I accept the recommendation of the RAC and the USDA Recombinant DNA Committee; and Appendix D of the NIH Guidelines is amended to reflect this decision.

II. Summary of Action

The following new section is added to Appendix D of the NIH Guidelines:

Appendix D-XI. Agracetus of Middelton, Wisconsin, may field test under specified conditions disease resistant tobacco plants prepared by recombinant DNA techniques.

Dated: September 25, 1985.

James B. Wyngaarden, M.D.,

Director, National Institutes of Health.

[FR Doc. 85-26916 Filed 11-12-85; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. N-85-1563]

Senior Executive Service; the Performance Review Board

AGENCY: Office of the Secretary, Department of Housing and Urban Development.

ACTION: Notice of appointments.

SUMMARY: The Department of Housing and Urban Development announces the appointments of Alfred C. Moran, John P. Kennedy, and Janet Hale (alternate member) to the Departmental Performance Review Board. Mr. Moran is the Assistant Secretary for Community Planning and Development, Office of Community Planning and Development; Mr. Kennedy is the Associate General Counsel for Program Enforcement, Office of General Counsel; and Ms. Hale is the General Deputy Assistant Secretary for Housing, Office of Housing. Their address is Department of Housing and Urban Development, Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Persons desiring any further information about the Performance Review Board and its members may contact Gail L. Lively, Acting Deputy Director of Personnel and Training, Department of Housing and Urban Development, Washington, D.C. 20410, telephone (202) 755-5500. (This is not a toll-free number.)

Dated: November 7, 1985.

Samuel R. Pierce, Jr.,

Secretary, Department of Housing and Urban Development.

[FR Doc. 85-26977 Filed 11-12-85; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

List of Indian Estates Affected by Old Age Assistance Claims; Notice of Reimbursement

November 4, 1985.

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Deputy Assistant Secretary—Indian Affairs by 209 DM 8.

SUMMARY: This notice lists trust estates identified by tribes, groups, individual Indians, and the Department of the Interior, from which unauthorized disbursements were made by the Secretary of the Interior to States, or political subdivisions thereof, as reimbursement for old age assistance provided to deceased Indians before death in violation of Federal laws. This notice is required by section 4(d) of the Old Age Assistance Claims Settlement Act of October 19, 1984, Pub. L. 98-500. The list appearing in this notice, together with the list of estates published in the Federal Register on April 17, 1985 (Vol. 50, No. 74, Part II), constitute all of the estates affected by old age assistance claims which have been identified for reimbursement. This notice also lists those estates, appearing in the Federal Register publication of April 17, 1985, which have been corrected and modified, or deleted as a result of the discovery of new or additional data.

FOR FURTHER INFORMATION CONTACT:

Aberdeen Area Director, Bureau of Indian Affairs, 115 4th Avenue, S.E., Aberdeen, South Dakota 57401, Telephone: (605) 225-0250;

Albuquerque Area Director, Bureau of Indian Affairs, 5301 Central Avenue, N.E., P.O. Box 8327, Albuquerque, New Mexico 87198, Telephone: (505) 766-3170;

Andarko Area Director, Bureau of Indian Affairs, Federal Building, P.O. Box 368, Anadarko, Oklahoma 73005, Telephone: (405) 247-6673;

Billings Area Director, Bureau of Indian Affairs, 316 North 26th Street, Billings, Montana 59101, Telephone: (406) 657-6315;

Eastern Area Director, Bureau of Indian Affairs, 1951 Constitution Avenue, N.W., Washington, D.C. 20245, Telephone: (703) 235-2571;

Juneau Area Director, Bureau of Indian Affairs, Federal Building, P.O. Box 3-8000, Juneau, Alaska 99802, Telephone: (907) 586-7177;

Minneapolis Area Director, Bureau of Indian Affairs, Chamber of Commerce Building, 15 South Fifth Street, 10th Floor, Minneapolis, Minnesota 55402, Telephone: (612) 349-3631;

Muskogee Area Director, Bureau of Indian Affairs, Old Federal Building, Muskogee, Oklahoma 74401, Telephone: (918) 687-2295;

Navajo Area Director, Bureau of Indian Affairs, P.O. Box M, Window Rock, Arizona 86515, Telephone: (602) 871-5151;

Phonix Area Director, Bureau of Indian Affairs, 3030 North Central, P.O. Box 7007, Phoenix, Arizona 85011, Telephone: (602) 241-2305;

Portland Area Director, Bureau of Indian Affairs, 1425 Irving Street, N.E., Portland, Oregon 97208, Telephone: (503) 231-6702 and

Sacramento Area Director, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, California 95825, Telephone: (916) 978–4691.

SUPPLEMENTARY INFORMATION: The Old Age Assistance Claims Settlement Act, Pub. L. 98–500, authorizes and directs the Secretary of the Interior to pay entitled individuals their portions of any unauthorized disbursement made from the trust estate of a deceased Indian to a State, or a political subdivision thereof, as reimbursement for old age assistance provided to the deceased Indian before death in violation of Federal laws governing Indian trust property. The Secretary of the Interior is further directed to search the records of the Department of the Interior to identify individuals who are entitled to payment, and to ascertain the amount of the unauthorized disbursement to which each of the individuals would be entitled. Any payment under the Act shall include simple interest at a rate of five percent per annum from the date on which such unauthorized disbursement was made from the trust estate of the deceased Indian. No payments shall be made with respect to any unauthorized disbursement from the trust estate of a deceased Indian if the total amount of such unauthorized disbursement was less than $50.

This notice lists Indian trust estates, identified by tribes, groups, individual Indians and the Department of the Interior, from which unauthorized disbursements were made for the purpose of reimbursement for old age assistance. Estates listed in this notice are divided into three categories: (1) Estates identified since publication of the first list in the **Federal Register** on April 17, 1985, (2) estates appearing on the first list which have been corrected and modified, and (3) estates deleted from the first list as a result of the discovery of new or additional data.

The payment and acceptance of any claim, after its determination in accordance with the Act, shall be a full discharge to the United States and any State, or political subdivision thereof, of all claims and demands touching any of the matters involved in the controversy.

Because of the numerous estates listed in the doucment, this notice may be subject to technical clarification or change.

Hazel E. Elbert,

Acting Deputy Assistant Secretary—Indian Affairs.

Instruction Sheet

Each estate from which an unauthorized payment was made has been assigned a nine or ten character issue number (a letter followed by eight or nine numbers). The first six characters identify a specific Bureau of Indian Affairs Area Office, Agency Office and tribe. The last three or four characters represent the specific numbers assigned to that estate from which an unauthorized payment was made. For example, A013400001 indicates:

A01—Aberdeen Area Office/Cheyenne River Agency
340—Cheyenne River Sioux Tribe
0001—Estate number one

To locate an estate, begin with the Table of Contents which lists each affected tribe (grouped by Area Office and Agency) and the pages where the estates for individuals affiliated with such tribe can be found. The list of estates has been reproduced by photographing two pages of the list to each **Federal Register** page. The page number referred to in the Table of Contents is located at the top center above the name of the Area Office and is not the five digit **Federal Register** page number located on the outer portion of each page.

If a tribe is not listed in the Table of Contents, no estate was identified for any individual affiliated with such tribe.

Each page of estates contains five columns of information under the headings: Issue Number, Decedent Name, Decedent ID, $ Allowed, $ Paid.

Issue Number: The nine or ten character code (explained above) which identifies the Area Office/Agency/Tribe/ and specific number assigned to that estate.

Decedent Name: The name of the deceased Indian whose Departmental records contain evidence that an unauthorized payment was made from his/her trust estate as reimbursement for old age assistance.

Decedent ID: The decedent's identification number. This number usually coincides with the decedent's allotment number, tribal enrollment number, or, in their absence, a number assigned by the Bureau of Indian Affairs.

$ Allowed: The amount of money, cited in the decedent's probate order, which was allowed as a claim to be paid from the decedent's trust estate as reimbursement to the State, or political subdivision thereof, for old age assistance. This figure appears in the list as an indication that the Departmental records contain evidence that some money was actually paid from the decedent's trust estate as reimbursement for old age assistance.

$ Paid: the mount of money actually paid (the amount of the unauthorized disbursement) from the decedent's trust estate as reimbursement to the State, or political subdivision thereof, for old age assistance. This figure is supported by evidence appearing in Departmental records. Where the Departmental records contain evidence that money was paid from the decedent's trust estate as reimbursement for old age assistance, but the exact amount is not known, the word UNKNOWN appears in this column; further research is neded to ascertain such amount.

If, after locating an estate on the list, you desire further informaiton, call or write the Area Office under shich the estate is listed. The names, addresses, and telephone numbers for all ARea Offices are contined in the **FOR FURTHER INFORMATION CONTACT** section of this document. Be sure to incldue the complete issue number in any correspondence with the Bureau of Indian Affairs area or agency office.

BILLING CODE 4310-02-M

TABLE OF CONTENTS

TRIBE CODE	AGENCY	TRIBE NAME	PAGE
ABERDEEN AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST			
A01-340	CHEYENNE RIVER	CHEYENNE RIVER SIOUX	1
A04-301	FORT BERTHOLD	FORT BERTHOLD	1
A05-303	FORT TOTTEN	DEVILS LAKE	1
A06-344	PINE RIDGE	PINE RIDGE SIOUX	1-2
A07-345	ROSEBUD	ROSEBUD SIOUX	2-3
A08-346	YANKTON	YANKTON SIOUX	3
A09-347	SISSETON	SISSETON-WAHPETON TRIBE OF SIOUX	3-4
A10-302	STANDING ROCK	STANDING ROCK SIOUX	4
A11-304	TURTLE MOUNTAIN	TURTLE MOUNTAIN BAND OF CHIPPEWA	4-5
A13-380	WINNEBAGO	OMAHA OF NEBRASKA	5
A13-382	WINNEBAGO	SANTEE SIOUX OF NEBRASKA	5
A13-383	WINNEBAGO	WINNEBAGO OF NEBRASKA	5
A14-342	CROW CREEK	CROW CREEK	5
A15-343	LOWER BRULE	LOWER BRULE SIOUX	5
ABERDEEN AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED			
A01-340	CHEYENNE RIVER	CHEYENNE RIVER SIOUX	6
A05-303	FORT TOTTEN	DEVILS LAKE	6
A06-344	PINE RIDGE	PINE RIDGE SIOUX	6
A07-345	ROSEBUD	ROSEBUD SIOUX	6
A08-346	YANKTON	YANKTON SIOUX	6
A09-347	SISSETON	SISSETON-WAHPETON TRIBE OF SIOUX	6-7
A10-302	STANDING ROCK	STANDING ROCK SIOUX	7
A11-304	TURTLE MOUNTAIN	TURTLE MOUNTAIN BAND OF CHIPPEWA	7
A13-380	WINNEBAGO	OMAHA OF NEBRASKA	7
A13-382	WINNEBAGO	SANTEE SIOUX OF NEBRASKA	7
A13-383	WINNEBAGO	WINNEBAGO OF NEBRASKA	7
A14-342	CROW CREEK	CROW CREEK	7
A15-343	LOWER BRULE	LOWER BRULE SIOUX	7
ABERDEEN AREA: ESTATES DELETED FROM FIRST LIST			
A00-007	FLANDREAU	FLANDREAU	7
A04-301	FORT BERTHOLD	FORT BERTHOLD	7
A05-303	FORT TOTTEN	DEVILS LAKE	7
A06-344	PINE RIDGE	PINE RIDGE SIOUX	7
A10-302	STANDING ROCK	STANDING ROCK SIOUX	7
A11-304	TURTLE MOUNTAIN	TURTLE MOUNTAIN BAND OF CHIPPEWA	7
A14-342	CROW CREEK	CROW CREEK	7
A15-343	LOWER BRULE	LOWER BRULE SIOUX	7
ANADARKO AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED			
B04-862	HORTON	POTAWATOMI (KANSAS)	8
B04-863	HORTON	SAC AND FOX (KANSAS AND NEBRASKA)	8
ANADARKO AREA: ESTATES DELETED FROM FIRST LIST			
B04-860	HORTON	IONA (KANSAS AND NEBRASKA)	8
B04-861	HORTON	KICKAPOO (KANSAS)	8
B04-862	HORTON	POTAWATOMI (KANSAS)	8
BILLINGS AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST			
C51-201	BLACKFEET	BLACKFEET	8
C56-204	FORT BELKNAP	FORT BELKNAP	8
BILLINGS AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED			
C51-201	BLACKFEET	BLACKFEET	8
C52-202	CROW	CROW	8
C56-206	FORT PECK	FORT PECK	8-9
C57-207	NORTHERN CHEYENNE	NORTHERN CHEYENNE	9

TABLE OF CONTENTS (cont)

BILLINGS AREA: ESTATES DELETED FROM FIRST LIST			
C51-201	BLACKFEET	BLACKFEET	9
C52-202	CROW	CROW	9
C55-204	FORT BELKNAP	FORT BELKNAP	9
C56-206	FORT PECK	FORT PECK	9
C57-207	NORTHERN CHEYENNE	NORTHERN CHEYENNE	9
MINNEAPOLIS AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST			
F52-409	MINNESOTA	RED LAKE	10
F53-407	MINNESOTA	LEECH LAKE OR GRAND PORTAGE OR RED LAKE	10
F53-408	MINNESOTA	WHITE EARTH	10
MINNEAPOLIS AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED			
F53-404	MINNESOTA	BOIS FORTE	10
F53-405	MINNESOTA	BOIS FORTE OR FOND DU LAC	10
F53-407	MINNESOTA	LEECH LAKE OR GRAND PORTAGE OR RED LAKE	10
F53-408	MINNESOTA	WHITE EARTH	10
F55-430	GREAT LAKES	BAD RIVER BAND OF THE LAKE SUPERIOR CHIPPEWA	10
F55-431	GREAT LAKES	LAC COURTE OREILLES BAND OF LAKE SUPERIOR CHIPPEWA	10
F55-436	GREAT LAKES	ST. CROIX CHIPPEWA OF WISCONSIN	10
F55-439	GREAT LAKES	WISCONSIN WINNEBAGO	10
MINNEAPOLIS AREA: ESTATES DELETED FROM FIRST LIST			
F53-405	MINNESOTA	BOIS FORTE OR FOND DU LAC	10
F53-407	MINNESOTA	LEECH LAKE OR GRAND PORTAGE OR RED LAKE	10
F53-408	MINNESOTA	WHITE EARTH	10
PORTLAND AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED			
P06-117	OLYMPIC PENINSULA	QUINAULT	10
P11-124	YAKIMA	YAKIMA	10
PORTLAND AREA: ESTATES DELETED FROM FIRST LIST			
P06-120	OLYMPIC PENINSULA	SKOKOMISH	10
P11-124	YAKIMA	YAKIMA	10
P12-102	SPOKANE	SPOKANE	10

PAGE 1

ABERDEEN AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
A013400003	MAGGIE PRETTY BUFFALO	734	841.50	841.50
A013400004	BESSIE SLIDES OFF	2082	3613.50	3613.50
A013400060	EDITH BLACK SHIELD	1698	2489.50	2489.50
A013400120	THOMAS IRON BIRD	776	435.50	435.50
A013400139	JAMES SPOTTED HORSE	849	34.37	34.37
A013400161	SARAH WHITE EAGLE WOMAN	3004	1978.00	2091.36
A013400187	GEORGE FISHERMAN	328P294	135.51	135.51
A013400188	KATE BLUE LEGS	379	1979.60	97.58
A013400189	HARRY KILLS TWICE	1123	1902.00	1902.00
A013400190	FELIX SPOTTED HORSE	440	1243.50	UNKNOWN
A013400191	ABRAHAM TAKES THE BOW	1115	2511.50	UNKNOWN
A013400192	RUSSELL SPOTTED BEAR	384	42.00	42.00
A013400194	JACOB LITTLE SKUNK	738	1066.00	1066.00
A013400195	PHILLIP BLACK MOON	1200	2175.00	656.72
A013400198	ELLEN SPOTTED BEAR	2777	263.60	197.70
A013400199	SARAH TURTLE	2921	1036.00	1036.00
A013404931	JOHN YELLOW SHOULDER	2546.5	337.60	337.60
A043010071	HOWARD MANDAN	503	1216.00	1216.00
A043010082	RICHARD BURR	409	1602.00	1602.00
A043010087	ANNA BAKER	17	0.00	128.00
A043010201	WILLIAM LITTLE OWL	499	672.00	208.92
A043010202	IRON WOMAN	1701	1172.00	1172.00
A043010203	DRAGSWOLF	111	200.00	200.00
A043010204	ELIZABETH MANY BEARS WHITE BEANS	1244	395.00	395.00
A043010205	JOSEPHINE GRINNELL	189	670.00	UNKNOWN
A043010206	EVA BIRD BEAR BEAKS	431	39.00	39.00
A043010207	JOSEPH HARRIS	473	180.00	180.00
A043010208	MOVES SWEET GRASS	526	238.00	168.06
A043010209	JESSE MASON SR.	531	1.00	UNKNOWN
A043010210	THAD MASON	551	609.50	UNKNOWN
A043010211	EDWARD BADGER	626	676.42	UNKNOWN
A043010212	ANDREW LITTLE CROW	702	207.00	207.00
A043010213	LINCOLN NEWMANN	713	488.70	UNKNOWN
A043010214	GRACE PARKER DEANE	783	53.00	53.00
A043010215	CLAIR EVERETT	831	740.50	740.50
A053030213	JOHN CRAZY DOG	221	395.00	395.00
A063440094	JOSEPH MESTETH	7823	50.00	UNKNOWN
A063440101	CLOUD	6649	406.60	406.60
A063440120	STRONG TALK	1148	215.50	215.50
A063440170	JOHN KILLS ENEMY	6028	576.40	578.44
A063440295	SUSIE CONQUERING BEAR	5244	1378.38	1378.38
A063440333	LYDIA TURNING BEAR	6188	1162.88	1162.88
A063440396	STANDING BEAR	4645	109.72	109.72
A063440397	PHILLIP MARSHALL	4527	100.00	100.00
A063440399	RED ELK	5648	488.20	490.20
A063440420	CONRAD WAR BONNET	466	256.43	256.43
A063440421	FRED OUT GRASS	443	1587.00	1587.00
A063440435	LIZZIE EAGLE LOUSE	3410	840.00	840.60
A063440439	SALLIE RED EAR HORSE	3360	2076.56	2076.56
A063440448	JAMES RED CLOUD	2875	1166.94	710.56
A063441443	LULU BIRD NECKLACE	6481	810.00	810.00
A063441444	MAUD LITTLE	7633	1838.95	1838.95
A063441445	SADIE NEW HOLY	7037	690.00	690.00
A063441446	ADA NOSE	3804	842.50	842.50
A063441447	JENNIE SIERS	4842	1547.75	1547.75
A063441448	MARY YELLOW WOOD WHITE HORSE	222	100.00	100.00
A063441452	LITTLE KILLER	7293	70.00	70.00
A063441459	LUKE POOR THUNDER	7209	1035.50	151.85
A063441461	JOSEPH BROKEN ROPE	3591	1415.77	1415.77
A063441471	HELEN TWO DOGS HORSE	3715	625.25	625.25
A063441472	JULIA GALLIGO	2786	738.91	738.91
A063441480	JOSHUA SPOTTED OWL	7523	448.00	436.59
A063441481	WILLIAM COLHOFF	288	1.00	1.00
A063441482	JOSEPH HORNBECK	835	229.70	229.70
A063441483	CHARLES YELLOW BOY	217	388.00	368.59
A063441484	JOHN CROSS DOG	328	432.50	432.50
A063441485	CHARLES SPOTTED EAGLE	1053	47.50	UNKNOWN
A063441486	JAMES LITTLE SOLDIER	900	861.00	861.00
A063441487	JULIA GHOST BEAR	6881	1931.50	1931.50
A063441488	STELLA FAST THUNDER KING	6438	742.31	742.31
A063441489	LAURA WOODLOCK	4645	109.72	109.72
A063441490	WILLIAM SPOTTED CROW	4720	854.22	854.22

PAGE 2

ABERDEEN AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST (cont)

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
A063441491	LOUISA RUSSELL	4824	1200.00	1200.00
A063441492	MILLIE (MARY) BULIMAN	4980	585.00	585.00
A063441493	CREIGHTON BROKEN ROPE	5031	730.84	730.84
A063441494	JESSIE BEAR ROBE	6461	541.70	541.70
A063441495	ADOLPH LONE ELK	6819	2332.50	2332.50
A063441496	JOHN BROWN THUNDER	6864	70.00	70.00
A063441497	ALICE STRAIGHT FOREHEAD	6902	613.88	613.88
A063441498	JESSIE PLEASES HERSELF	6940	1554.29	1554.29
A063441499	ELLA WHITE BULL	6958	883.00	883.00
A063441500	JOHN YELLOW HAWK	5354	217.00	217.00
A063441501	LOUIS JUMPING BULL	6403	3229.50	3299.50
A063441502	STRAIGHT FOREHEAD	6433	11.84	11.84
A063441503	ALICE(BOYER) LAYS BAD	3946	232.00	232.00
A063441504	CHARLES STINKING BEAR	3338	898.87	898.87
A063441505	JOHN RED SHIRT	3449	82.59	82.59
A063441506	LIZZIE FEATHERMAN	3776	550.00	550.00
A063441507	ROSA CHARGING CROW	1801	288.00	288.00
A063441508	HERBERT HOLY ELK	1909	64.00	64.00
A063441509	HENRY WHITE HORSE	2431	460.50	460.50
A063441510	JOSEPHINE (DAY) MEANS	7164	512.00	512.00
A063441511	HER DOOR WHISTLER	7193	741.15	741.15
A063441512	MAY STABBLER	7239	28.00	28.00
A063441513	JOHN KILLS FIRST	7378	709.36	679.84
A063441514	ANNIE BLACK BEAR	7379	462.75	445.05
A063441515	WALLACE CHARGING CROW	7030	674.00	674.00
A063441516	JULIA STRIKES PLENTY	7072	250.00	250.00
A063441517	ALICE PINE BIRD	7094	2070.70	2070.70
A063441518	GEORGE TWO EAGLES	7100	1953.00	1953.00
A063441519	THOMAS HOLLOW HORN	7557	1.00	1.00
A063441520	LUCY LITTLE HORSE	7448	1505.00	1505.00
A063441521	POUTING	7565	991.85	991.85
A063441522	JESSIE TWO EAGLE	7627	1033.00	1033.00
A063441523	SAMUEL EAGLE HAWK	6144	1339.00	226.67
A063441524	LILY POOR BUFFALO	6490	497.60	497.60
A063441525	FANNIE JANIS	9760	48.00	48.00
A063441526	MILLIE MOUNTAIN SHEEP	3502	785.00	785.00
A063441528	MARY LAKOTA	7436	321.77	UNKNOWN
A063441529	RICHARD RUNNING BEAR	4854	291.20	UNKNOWN
A063441530	ALICE WOLF EARS	6024	3590.00	UNKNOWN
A063441531	JENNIE TAKES WAR BONNET	1592	220.00	UNKNOWN
A063441532	VALENTINE HERNANDEZ	1411	1.00	UNKNOWN
A063441533	WILLIAM PLENTY ARROWS	5423	47.50	UNKNOWN
A063441534	LENA BROWN BULL	5844	900.00	UNKNOWN
A063441535	HELENA TWO TWO	8052	810.95	810.95
A063441536	AMELIA YOUMAN	4697	10.00	10.00
A073450010	GOOD ELK	1787	552.20	667.66
A073450017	ALLICE COMES OUT FIRST	4132	2757.00	2757.00
A073450025	RUNNING BEAR	5976	948.00	948.00
A073450043	WILLIAM SHARP BUTTE	3248	1485.50	1485.50
A073450058	AMOS CHASING HAWK	2811	724.20	724.20
A073450080	KATE RUNNING BIRD	1320	20.00	25.21
A073450094	THOMAS KILLS THE ENEMY COOL	1152	501.20	501.20
A073450131	TIED HAIR KNOTTS	3978	820.00	429.12
A073450181	ALFRED BONESHIRT	3677	1105.80	1138.42
A073450218	CLOUD BOY	1147	654.73	654.73
A073450220	CHARLES CAMPBELL	1190	1725.00	1725.00
A073450225	PHILLIP LARVIE	2175	705.60	705.60
A073450299	LOUISE SITTING BIRD OR HER CRANE	2638.5	723.00	723.00
A073450805	LUCY LONG PUMPKIN TALKING	2235.5	5.00	6.00
A073450814	MATTHEW GOOD ELK	2533	448.31	448.31
A073450842	WILLIAM STRANGER HORSE	135	84.00	84.00
A073450843	WINNIE NIGHT PIPE	175.5	1117.47	1117.47
A073450844	NELLIE AFRAID OF BEAR	192.5	277.08	277.08
A073450845	RICHARD D. ELLSTON	240	247.00	UNKNOWN
A073450846	SAM BORDEAUX	596	250.20	95.85
A073450847	THERESA BRIDGEMAN	1040.5	136.00	136.00
A073450848	MRS. MARY MCLEAN	369	118.50	118.50
A073450849	THOMAS YELLOW BULL	1117	3400.00	UNKNOWN
A073450850	DORA BLUE WHIRLWIND	1238.5	122.71	122.71
A073450851	MRS. RICHARD LIPP	1331	40.04	UNKNOWN
A073450852	FANNIE WHITE HAWK	1429	122.00	122.00
A073450853	GLADYS IRON SHELL	1431	61.50	40.64
A073450854	BRAVE	1597	52.12	UNKNOWN

ABERDEEN AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST (cont)

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
A073450855	THOMAS LARVIE	1601	187.25	187.25
A073450856	GEORGE POOR THUNDER	1624	1000.00	UNKNOWN
A073450857	WILLIAM WHITE HAWK SR.	1788	1488.00	UNKNOWN
A073450858	MINNIE BIG CROW	1879	950.00	UNKNOWN
A073450859	ALICE QUICK BEAR	2064	185.76	185.76
A073450860	MARTHA CLOUDMAN	2257.5	460.03	UNKNOWN
A073450861	LIZZIE COLOMBE	2299.5	1200.00	UNKNOWN
A073453161	CHARLES REE	2518	87.46	87.46
A073453162	CHARLES PICKET PIN	2522	400.00	400.00
A073453163	ROSE CREKPA	2559	81.00	UNKNOWN
A073453164	JOHN GASSMAN	2671	65.00	65.00
A073453165	JAMES LOOKING EAGLE	2858	281.00	UNKNOWN
A073453166	SAM RED HORSE	3297	12.00	UNKNOWN
A073453167	EAGLE DEER (HOLY OWL)	4008.5	516.00	UNKNOWN
A073453168	HERMINE KILLS THE ENEMY	4094.5	655.00	480.13
A073453169	SWEAT HOUSE	4127	493.73	493.73
A073453170	CENTER	5976	948.00	UNKNOWN
A073453171	HAZEL MEDICINE OWL	3959	651.80	562.54
A083460014	MARY SARAH GASSMAN	311	679.70	679.70
A083460047	EMILY IRON HAWK	956	322.00	322.00
A083460054	FRED FREDERICK	98	650.00	650.00
A083460060	EDWARD CHAMBERLAIN	815	360.50	360.50
A083460409	DANIEL BUSUNA	47	271.50	UNKNOWN
A083460410	FRANK DRAPEAU SR.	1176	5.00	UNKNOWN
A083460411	LEAH DOG BOY	814	238.70	UNKNOWN
A083460412	JOHN DRAGG	290-1018	6518.00	412.78
A083460413	NARCISSE DRAPEAU	1180-B	2715.00	2700.50
A083460414	JOHN W. HAPE	175-800	1184.35	654.55
A083460415	LOUISA HOPE	646	16.17	UNKNOWN
A083460416	NANCY JORDAN	794	1838.00	1797.77
A083460417	JOHN O'CONNOR	1066	5.00	5.00
A083460418	JOSHUA PRETTY BULL	582	4782.50	1219.05
A083460419	MARY SITTING CLOUD	1174	594.00	UNKNOWN
A083460420	OSOTEWIN	127	162.00	UNKNOWN
A083460421	EMMA LEROY	697-67	4943.00	697.35
A083460422	PETER FELICIA	329-852	3087.50	1034.77
A083460423	ADELIA STRICKER	B-309-61	619.33	619.33
A083460424	OSCAR BERNIE	990	276.00	170.67
A093470030	THOMAS BLUECLOUD	1184	1346.20	794.85
A093470032	SAMUEL DERBY	1311	1467.80	1467.80
A093470052	PHOEBE M. QUINN SAUL	639	2.46	2.46
A093470421	EVA DE MARRIAS WILLIAMS JONES	D658	7148.00	238.69
A093470422	JULIA RONDELL OWENS	149	2350.50	12.63
A093470423	BELLE SHELDON BARSE	584/1209	5860.00	446.38
A093470424	WILLIAM ROBERTSON	515	1716.50	40.27
A093470425	ANDREW SHEPHERD	317	4962.00	678.72
A093470426	SAMUEL ADAMS	90796	265.35	265.35
A093470427	MARY ALEXIS	1114	1882.89	1882.89
A093470428	CHARLES BARKER	99	897.00	897.00
A093470429	ADAM BERNARD	445&1092	956.50	956.50
A093470430	NANCY BLUE CLOUD	1275	1630.00	677.25
A093470431	ANDREW BROWN	822-880	774.00	774.00
A093470432	JOHN BUFFALO JR.	91257	144.00	144.00
A093470433	EMMA BURKE	90203	3433.50	1879.37
A093470434	DANIEL CAMPBELL	120062	3351.50	373.73
A093470435	PETER CRAWFORD	79-242	5022.00	237.64
A093470436	ISABELLE DECOTEAU	449-587	5229.50	275.95
A093470437	JOHN DAVID	499	1657.00	1657.00
A093470438	JENNIE DERBY	1294	935.30	935.30
A093470439	SAMUEL DU MARCE	173-678	6158.50	167.72
A093470440	MARY TIOMANIPI GOODTEACHER	92-703	1785.11	1785.11
A093470441	ANNA GOOD VOUCE	820-877	3895.00	638.90
A093470442	SARAH GRAY BUFFALO	429	342.96	342.96
A093470443	HORACE GREELEY	1341	2537.45	1143.00
A093470444	JAMES OR CASKE HAYES	1068	805.85	805.85
A093470445	JULIA WAY HAYES	329	2241.25	1471.61
A093470446	LOUIS T. HILL	90824	3004.50	3004.50
A093470447	JAMES HORN	4736&617	2054.00	2054.00
A093470448	ELIZA RENVILLE IRVING	90887	849.50	849.50
A093470449	FRANK ISAAC	1021	1787.63	1787.63
A093470450	SUSAN JAMES	1224	111.40	111.40
A093470451	JOSHUA JOHNSON	550-930	541.00	541.00

ABERDEEN AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST (cont)

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
A093470452	MABEL MAX JOHNSON	1726&677	32.00	32.00
A093470453	WILLIAM JOHNSON	929	399.50	399.50
A093470454	JOHN KING	182	420.00	420.00
A093470455	SAM SIMON KING	90070	2129.50	1390.73
A093470456	SIMON J. KIRK	1127&1216	1838.00	325.25
A093470457	BAPTISTE LAPELLE	322-1358	80.02	80.02
A093470458	ELLEN OR ELLA LABELLE	1072	594.00	579.42
A093470459	GLODE LA FROMBOISE	1360	681.00	371.85
A093470460	JOHN LITTLE THUNDER	10-40	797.00	797.00
A093470461	SOPHIA LOVEJOY HOPKINS	434	1150.00	1150.00
A093470462	JACOB (EARTH) MAKA	48-685	320.00	320.00
A093470463	SAMUEL NAHOTON	501&981	667.00	667.00
A093470464	ELIZABETH NOBLE	444-612	3996.00	1747.32
A093470465	ALICE ONIHAN	309	1950.50	959.92
A093470466	JOHN PIPIYA	641	1572.00	749.11
A093470467	ALICE ORTLEY	375	2096.00	70.66
A093470468	MATTHEW OR MATHIAS PHELPS	25	1694.50	1300.61
A093470469	JOHN JAMES PLUME	7706896	637.50	637.50
A093470470	DANIEL RED EARTH	1272	267.98	267.98
A093470471	SAMPSON RENVILLE	59	11789.77	184.49
A093470472	AMOS ROBERTS	90462	64.00	64.00
A093470473	CEXPU-MARY ROUILLARD	917	823.23	823.23
A093470474	HENRY RUPAHUSDA	1252	191.00	191.00
A093470475	WILLIAM SINTENA	911	1022.23	1022.23
A093470476	ENOCH SIMONS	536-996	2332.50	2332.50
A093470477	LOUISA SIMONS	160	6039.00	546.39
A093470478	ALEXANDER SPIDER	387-805	5110.00	436.73
A093470479	SALEM WHITE	417-1015	3801.50	1292.67
A093470480	AUGUSTA WILLIAMS	949-1056	302.00	302.00
A093470481	MARY WILSON	484	2881.98	2281.98
A093470482	NANCY WILSON	421	952.94	952.94
A093470483	ROSE REDDAY WILSON	396	159.00	159.00
A093470484	JAMES RENVILLE	646&1189	3879.50	UNKNOWN
A093470486	GEORGE CLOUTIER	722	5058.50	UNKNOWN
A093470487	LUCY RYAN	333	4536.06	UNKNOWN
A093470488	CHARLES WHITE	350-891	1700.00	UNKNOWN
A093470489	AMOS SKYMAN	406	298.90	UNKNOWN
A093470490	PAUL WING	511-763	4224.50	UNKNOWN
A093470491	JESSIE MARTIN	1297	4745.00	UNKNOWN
A093470492	ANNA TAYLOR	1335	8921.50	UNKNOWN
A093470493	LYDIA SEABOY	1337	245.00	245.00
A093470494	ALICE CRAWFORD	160	714.16	UNKNOWN
A093470495	IDA KAMPESKA	1002	286.00	286.00
A093470496	ELIZABETH STUART	2453	169.49	169.49
A093470497	AMOS KING	67	4821.00	UNKNOWN
A103020005	MRS. CHARLES IRON HORN	3651	752.10	233.80
A103020007	MRS. JAMES AMIDST	3641	2555.41	2555.41
A103020008	MRS. GUS RED EAGLE	3613	616.50	616.50
A103020012	MRS. OLIVER SLEEPS FROM HOME	3584	394.50	394.50
A103020048	ABRAHAM BUCKLEY	1115	2511.50	2511.50
A103020057	JOHN CRAZY BEAR	1374	1366.86	1366.86
A103020098	ANSLEM KILLS CROW	402	40.00	40.00
A103020111	MICHAEL SNOW	607	1553.50	1553.50
A103020119	AGNES LITTLE DOG	3255	505.50	505.50
A103020120	JULIA CRAZY HAWK	3257	315.30	315.30
A103020124	JULIA SEE THE BEAR	3322	934.30	934.30
A103020177	JOHN RUNNING HAWK	4577	18.00	18.03
A103020180	MARGARET FLY	2892	546.00	UNKNOWN
A103020183	BENEDICT CATCH BEAR	128	1278.00	1278.00
A103020233	JEROME STANDING SOLDIER	1865	376.00	376.00
A103021136	LUKE GOOD LEFT HAND	1917	307.84	UNKNOWN
A103021137	JOSEPH HAS HORNS	382	3621.40	3621.40
A113040001	AKEWENSI	45	3930.00	846.24
A113040004	JOHN AIKEN	191	63.49	43.06
A113040105	JOHN BAPTISTE ENNO	1136	7.87	7.87
A113040261	CHARLETTE SAYERS (PAINAUDE)	U9156	218.43	198.58
A113040263	JOHN PATRICE DELORME	1018	1112.00	UNKNOWN
A113040264	ISADORE AZURE	A352	239.21	239.20
A113040265	CLEOPHILE (GLADUE) ALLARD	293	8422.00	324.10
A113040266	MARGARET (CAMPION) AZURE	231	637.25	356.09
A113040267	ALBERT BOUCHER	B-172	1544.70	418.77
A113040268	JOHN DESJARLAIS	D-264	4356.00	1096.35

ABERDEEN AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST (cont)

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
A113040269	DRESSED IN YELLOW	O-11	537.14	537.14
A113040270	ROSIE (KLYNE) DUBRAY	K-80	40.87	22.56
A113040271	ALFRED FALCON	F-73	1662.13	169.95
A113040272	MATHILDA GOURNEAU	G-258	482.00	482.00
A113040273	HARRIET GRANT	1435	6145.00	477.40
A113040274	MARY LOUISE (MORIN) JEROME	J-33	516.00	516.00
A113040275	JOSEPH LAFONTAIN	L-171	500.00	6.97
A113040276	ROSALIE LAVALLIE	M-404	9483.00	120.00
A113040277	JOSEPH PILON	P-250	3467.00	120.78
A113040278	JOHN SKINNER SR	N-10	250.00	235.00
A113040279	LOUIS VALLIE	V-56	228.00	73.77
A113040280	YELLOW SKY	Z-2	367.71	102.21
A113040281	VIRGINIA MARION	U-8217	5110.00	UNKNOWN
A113040282	JOSEPH ALLARD	U-5139	4068.00	UNKNOWN
A113040283	JULIA PELTIER	U-12713	29.76	UNKNOWN
A113040284	SARAH ENNO	U-11258	380.18	UNKNOWN
A113040285	SYLVESTER SHORT	U-11068	182.00	UNKNOWN
A133800321	GENEVIEVE (BUFFALO) LOVEJOY	444-O	558.00	558.00
A133800893	LEVI LEVERING	473-O	821.08	821.08
A133800894	OLLIE MERRICK	90126	382.95	UNKNOWN
A133800895	IRENE GRANT	235-N	2955.93	UNKNOWN
A133800896	CHARLES WOODHULL	787-O	4897.40	UNKNOWN
A133800897	HENRY LOVEJOY	445-O/764-N	316.00	UNKNOWN
A133800898	FRANCES MITCHELL	407-N	366.40	UNKNOWN
A133820139	CHARLES LE CLAIRE	130	1627.50	1254.58
A133820141	AGNES (FRAZIER) GARNEAUX	664	14.50	UNKNOWN
A133820142	JULIA TRUDELL	471	6276.00	UNKNOWN
A133820143	SOPHIA WILSON/GENICK/CORDIER OR	382-G-279	6216.17	UNKNOWN
A133830124	MINNIE K. CLOUD PRIEST	U	1183.96	853.93
A133830587	JOSEPH EAGLE	R3194	208.30	UNKNOWN
A133830588	THOMAS DECORA JR.	305	2775.80	UNKNOWN
A133830589	JAMES CARAMONY	461	396.20	UNKNOWN
A133830590	ALBERT IOWA CROW	703	513.40	UNKNOWN
A133830591	PETER RAVE	383-R-82	224.36	101.19
A143420073	LIZZIE MEDICINE CROW	757	208.50	208.50
A143420170	HER CIRCLE	U-274	5.00	5.00
A143420171	MARY (HER CANE) BLACK BEAR	U-1010	5.00	5.00
A143420172	HER HORSE OR HARRIET HIS BATTLE	U-225	326.85	UNKNOWN
A143420173	CELESTE PAMANT/BLUE HAIR WOMAN	U-374	233.25	65.51
A143420174	MRS. PETER SARGEANT/SMALL WOMAN	U-535	106.05	106.05
A143420175	MRS. JULIA WALKING SHIELD	U-584	3625.00	1869.43
A143420176	MARY LITTLE CLOUD	U-183	302.00	UNKNOWN
A143420177	MEDICINE NEST (HOLY NEST)	U-332	200.00	UNKNOWN
A143420178	MEDICINE SHELL	U-331	5.00	5.00
A143420179	MOSES WOODPILER	94	161.68	161.68
A143420180	MRS. ANNA PLAYS WITH IRON	98	5.00	5.00
A143420181	MARY LOUDNER	U-299	16.18	16.18
A143420182	SHELL FACE/MRS. AFRAID OF BEAR	U-524	7.24	7.24
A143420183	MARTHA SIDE HILL	U-1075	5741.00	21.03
A143420184	JOHN SIDE HILL	195	385.00	UNKNOWN
A153430016	MARGARET SPOTTED BULL	479	616.00	616.00

ABERDEEN AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
A013400013	JAMES AFRAID OF LIGHTENING	1259	650.00	434.77
A013400027	OTTER ROBE MARY ALICE	2157	1133.00	222.97
A013400044	CURLEY FINTON	1203	510.70	306.36
A013400066	CECELIA CHARGING HAWK	472	3382.00	217.17
A013400067	LITTLE CROW, JESSIE (MRS. GEORGE	685	720.00	720.00
A013400073	RED BULL, ROSE (IRON LIGHTNING)	2180	220.00	220.00
A013400085	BLACK EAGLE, GRACE	1379	1466.50	1466.50
A013400115	AFRAID OF THE BEAR MAGGIE	355	241.16	241.16
A013400140	BULL EAGLE, JACK OR PAUL	1211	77.95	77.95
A013400148	BROWN WOLF/ OR FOLLOW HIM (MRS.	1071	36.46	36.46
A013400184	BLUE ARMS, MRS. KATE OR LAURA (C	2371	564.04	564.04
A053030100	BROWN, EUGENE	356	2959.00	774.27
A053030104	WAKAKSAN, NANCY (GUY)	509	867.15	439.50
A053030173	BLACKSHIELD, MARY	135	1266.00	1266.00
A053030174	MCKAY, LUKE B.	27	4900.00	1310.92
A053030219	JACKSON, JOSEPH	812	7234.00	336.95
A053030225	YOUNG, GEORGE	1135	323.20	93.58
A053030227	YOUNG, PETER	42	4897.00	749.74
A063440008	BISSONETTE, JOSEPH	2094	700.00	700.00
A063440026	LITTLE BEAR JENNIE	8215	568.00	568.00
A063440054	SUSIE MERRIVAL	3592	1600.00	130.74
A063440074	LITTLE KILLER/LIYTLE LEADER, JOH	2047	149.10	149.10
A063440067	RED BREATH BEAR, MILDRED	6430	355.00	355.00
A063440130	HIGH CAT, LEE	6532	150.00	150.00
A063440140	FIRE THUNDER, WILLIAM	943	1113.00	1113.00
A063440153	KATE ROMERO	8029	365.28	365.28
A063440204	DANA LONE WOLF	4889	2659.30	2659.30
A063440208	EAGLE LOUSE, JOHN	3411	2917.30	774.07
A063440226	PLUME, HOBART	5716	2514.50	2514.50
A063440241	LOOKING ELK, SYLVIA	3153	1489.50	1489.50
A063440325	DILLION, EMILY (STANDING BEAR)	4511	30.00	30.00
A063440326	STOVER, EDWARD	4636	7.35	7.35
A063440345	JOSEPH HIGH EAGLE	3454	2462.00	2426.50
A063440358	REDBEAR, JOSIE (OLD HAIR)	1223	43.91	43.91
A063440415	MOUSSEAU, LOUIS JR.	1856	94.00	94.00
A063440418	BACKBONE SPIDER, LUCY	6259	2868.45	2868.45
A063440434	LITTLE BEAR, HENRY	3638	1748.00	1748.00
A073450041	YELLOW CANE FAST BULL, SUSIE	2351	454.00	362.58
A073450057	YELLOW HAWK DORA HIGH DOG	2753	993.00	993.00
A073450063	MENARD, GEORGE	548	189.60	189.60
A073450064	PAWNEE, MARY	724	64.20	64.20
A073450085	DILLON, GEORGE	436	797.50	797.50
A073450114	JENNIE METCALF (BEAUVAIS)	489	1489.50	236.13
A073450123	HAWK, LUKE	401	5427.10	1744.47
A073450126	YELLOW FACE, LUKE	224	594.80	594.80
A073450158	CURTIS, FELIX	1586	106.71	106.62
A073450187	FIRE HEART BEAR, JULIAN	4139	718.00	718.00
A073450204	EAGLEMAN, ALFRED	1781	3767.00	623.48
A073450247	LONG ELK, WILLIAM	2771	616.00	616.00
A073450300	MINNIE USES HER WOPOS	2074	1749.00	1749.00
A083460034	HOMER REDLIGHTENING	1265	661.00	135.97
A083460044	JANDREAU, JULIA LONGBEAR	83	1235.00	906.39
A083460050	GRAY, ALICE	79	3974.00	399.43
A083460064	PATTERSON, ANNIE RAINBOW	542	2354.00	2354.00
A083460067	RUMNEY, ANNIE MATO HARE	675	524.50	524.50
A083460068	STINGER, FRANK REE	564	1130.50	913.87
A083460069	ASHES, SUSAN FEATHER	1068	353.50	353.50
A093470001	KEEBLE, ISAAC	1249	742.63	646.85
A093470002	PAUL ADAM	837	618.35	618.35
A093470003	STEADFAST, THOMAS	1271	3940.50	3623.69
A093470006	THOMAS HEMINGER	656	913.50	410.68
A093470008	BEAR, MARY	573	1356.34	1098.96
A093470009	STAFFORD, CECELIA (BARTLETT)	606	1464.93	1464.93
A093470010	REDEARTH, EMMA	632	4473.90	271.00
A093470012	GRANT, JENNIE	15	218.82	218.82
A093470015	RENVILL, SAMUEL	1004	4443.50	1116.56
A093470018	WHITE KING, ELLA	416	4227.63	787.66
A093470023	WILLIAMS, JOHN (SUNKA)	757	5270.50	532.10

ABERDEEN AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED (cont)

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
A093470027	BARSE, SARAH (RENVILLE)	1081	2048.50	2048.50
A093470039	GRAHAM, ZENOS	NE-842	750.00	750.00
A093470043	LABELLE, PETER	1236	301.00	301.00
A093470044	LACROIX, ALBERT	114	30.15	30.00
A093470053	SHEPHERD, HANNAH L.	314	54.25	54.25
A093470062	SPIDER, MARY (LOVEJOY)	167	866.30	552.75
A093470419	HANNAH BARKER REDEARTH	456	2269.00	1421.59
A093470420	AGNES FLUTE	1003	1668.00	1668.00
A103020004	EAGLEBOY, MRS. ROSE	3653	1011.00	1011.00
A103020009	NO HEART, JOSEPHINE GABE, SR	3602	500.00	228.87
A103020018	RED BIRD, NORA	3264	1237.00	1237.00
A103020020	EAGLE BOY, MRS. GROVER	3389	1263.00	1262.50
A103020028	JOSEPH EAGLEMAN	2647	1906.00	1924.18
A103020029	WHITESELL, JOHN	551	112.78	112.78
A103020113	IRON HORN, CHARLES	623	40.00	40.00
A103020127	KILLS CROW INDIAN, JULIA (MIDDLE	3338	1057.50	1057.50
A103020148	SPOTTED HORSE, FELIX	440	1243.50	1243.50
A103020161	CROSS, JULIA (MRS. WILLIAM)	3132	831.00	831.00
A103020166	IRON BULL MARTIN	2368	1516.00	1516.00
A103020179	DUNCAN, ELLEN	2833	2237.77	2232.77
A103020204	SHIELD NECKLACE, LEO	2402	49.00	UNKNOWN
A103020215	BLACKBEAR, CHARLES OR SMUTTY BEA	2321	3660.00	1920.89
A103020219	COMES LAST THOMAS (EHAKAKU)	2159	197.00	197.00
A103020297	BRISTLING, SOPHIE (MRS. LUCAS)	3057	25.35	25.35
A113040010	AZURE, JOSEPH	386	2889.00	282.64
A113040012	BELGARDE, JACQUES	471	450.00	300.00
A113040016	CHAMPAGNE, MARIE	740	3310.00	1797.91
A113040024	GORDON, LUCILLE (GARDNER)	1240	5017.00	2.47
A113040025	GOURNEAU, JOSEPH JR.	1253	3405.00	727.98
A113040027	LAVENDURE, LARASE VANDAL	N303	53.33	53.33
A113040038	LAFOURNAISE, PATRICK	1644	649.76	627.09
A113040055	MASON, JOSEPH	2025	2822.00	399.12
A113040069	PELTIER, BARTHALOMEW	2287	7156.00	190.23
A113040076	ROUSSIN, EUSTACHE	2515	475.00	529.62
A113040083	ST. PIERRE, MARTIN	2617	3577.00	3315.08
A113040104	TURCOTTE, MARY LOUISE	968	3961.00	2943.56
A113040254	WILKIE, PAULINE ALLARD	09885	567.00	0.95
A133800315	MITCHELL, THOMAS	758	1348.00	1010.53
A133800316	HARLAN, REUBEN	354	2028.20	2028.20
A133800318	PORTER, PHILLIP	750	507.80	424.92
A133800319	DICK JOSEPH	46-0	782.32	289.62
A133800323	WILLIAM WEBSTER CAYOU	845-0180-N	2561.92	1834.76
A133800324	SOLOMON HARRY	353	2407.43	1059.24
A133820140	BARKER, CHARLES	382	1714.00	UNKNOWN
A133830114	HENSLEY, MARTHA (HENRY)	41	1141.72	1065.27
A143420017	BLISS WOOD PILER, LEN	300	3768.50	860.25
A153430009	EVA DESHEUQUETTE	291	660.00	660.00
A153430010	QUILT, ANNIE (DRIVING HAWK)	292	2830.50	1710.59
A153430012	IRON ELK, ROSIE	101	3423.00	1521.82
A153430025	YELLOW EYES, HELEN	269	3334.50	630.73
A153430027	WALKING WOMAN, MARY	309	112.34	112.34

ABERDEEN AREA: ESTATES DELETED FROM FIRST LIST

A000070133 A043010209 A053030200 A053030201 A053030202 A053030203
A053030204 A053030205 A053030206 A053030207 A053030208 A053030235
A053030296 A063440255 A063440288 A063441469 A103020248 A103021135
A113040119 A113040240 A113040249 A143420061 A153030099 A153430100

ANADARKO AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
B048620135	JOE TURTLE	211	1952.56	308.97
B048620136	ALICE WAHWASSUCK	W-290	533.48	265.12
B048620146	MAGGIE WHITEFISH BARNEY	715	105.00	105.00
B048620148	WILLIE SHEKONE NESS	739	142.53	142.53
B048620149	SQUA SE ZHICK	S-39	615.00	269.22
B048630153	THOMAS GREEN	KG-34	964.50	964.50

ANADARKO AREA: ESTATES DELETED FROM FIRST LIST

B048600155 B048610150 B048610151 B048610152 B048620134 B048620138
B048620139 B048620141 B048620142 B048620143

BILLINGS AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
C512011504	PATRICK LAMERE	UA CREE	2475.00	417.75
C552040109	CALF GHOST	976	1820.84	1820.84

BILLINGS AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
C512010028	GEORGE BULLCHILD	1731	312.00	312.00
C512010029	PETER WHITEMAN	484	958.00	891.18
C512010030	MARY LOUISE REDFOX OLDROCK	2498	282.00	282.00
C512010032	AGNES ROSE	316	5044.25	2144.23
C512010036	VIRGINIA HOWARD BILLEDEAUX	1865	482.87	482.87
C512010047	HERMAN DOSTYBULL #1	1762	543.00	543.00
C512010051	UNDER BEAVER FLINT SMOKER	56	3027.25	946.55
C512010062	BAPTISTE MERCIER (RONDIN)	1710	360.40	343.85
C512010084	GOING AFTER WATER SHORTROBE	1422	1257.20	1257.20
C512010088	MINNIE WALTER	631	1488.00	1123.34
C512010092	MARY SUORTY	1430	2824.00	723.44
C512010107	MARY WAGNER	2196	631.00	605.38
C512010110	BAPTISTE WEST WOLF	1107	3263.00	3088.78
C512010113	HAIRY COAT	964	560.75	184.60
C512011445	LOUIS LITTLEPLUME	945	1466.00	860.00
C512011456	ELLEN LONECHIEF	1208	632.11	632.11
C512011474	ROBERT MANYHIDES	1909	3470.00	1389.05
C512011480	DORA DENNIS	2088	1025.00	1025.00
C512011482	WILLIAM HENKEL	2219	365.00	365.00
C512011485	CAROLINE HENKEL	2652	3838.00	696.54
C522020053	TAKES ENEMY	1	1061.00	201.58
C522020058	JOSEPHINE SHANE WHITECLAY	170SA	917.00	87.14
C522020070	YELLOW BROW	1310	532.00	532.00
C522020081	OLD CRANE	1956	422.75	368.46
C562060038	SAMUEL ALL SON	11	2305.25	2305.25
C562060040	HANNAH BOWSHIELDS	82	126.00	126.00
C562060041	SAMUEL CONGER	185	2288.00	2023.67
C562060042	ROSE CHASER CLEVELAND	161	1698.00	1698.00
C562060043	SOPHIA BURSHIA	145	191.00	191.00
C562060046	COUNTER	204	435.75	435.75
C562060047	GOODHAND CROW	215	878.75	878.75
C562060048	GOOD NEST DRUM	280	3589.75	1602.77
C562060049	MABEL CLARA KOON DUPREE	290	864.20	137.00
C562060052	JOHN G. FOOTE	338	130.50	130.50
C562060062	FRANK LONGEE	574	581.80	581.50
C562060063	ELLA LONGEE	575	1102.00	1102.00
C562060066	MEDICINE EAGLE	636	137.50	137.50
C562060076	SHADOW TAKES THEM	932	66.00	66.00
C562060082	JAMES WALKING EAGLE	983	1565.07	947.11
C562060101	USES JAW DIGS THE GROUND	1290	891.50	877.79
C562060108	TWO BONNETS	2805	4343.00	4343.00
C562060111	CAROLINE LAROQUE	1458	530.94	98.21
C562060116	JOSEPH MARTIN	1514	3667.50	3231.23
C562060131	ROBERT BUCK ELK	120	630.00	630.00

BILLINGS AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED (cont)

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
C562060132	WOOD HOWLING BIG FOOT	125	317.75	317.75
C562060134	WALKING CLOUD HALF RED	385	323.32	323.32
C562060136	NANCY MUSKRAT	679	50.00	50.00
C562060139	AGNES RED BOY	211	1958.50	1958.50
C562060140	ANDREW SHIELDS	656	4991.00	49.96
C562060144	WHITE SHIELD	1062	1033.75	1033.75
C562060146	CHARLES BLACK DOG	1154	429.00	429.00
C562060155	LODGEPOLE FOUR STAR (RUNS THRO	1352	1317.50	1317.50
C562060158	THOMAS HANCOCK	1395	318.00	318.00
C562060161	WHITE WOMAN ONE CLAW	1562	371.00	371.00
C562060162	JIM OLD ROCK	1563	385.00	385.00
C562060164	RED DOG THUNDERING WOMAN	1594	755.50	755.50
C562060165	JAMES ROBERTS	1615	1062.50	1062.50
C562060168	NECK WALKING BULL	1745	145.00	145.00
C562060172	JOHN LEFT HAND THUNDER	534	703.00	703.00
C572070041	AUSTIN TEXAS AMERICAN HORSE	5	5068.00	1164.25
C572070043	HELEN ANT	24	4168.00	396.75
C572070045	MARTHA PUNCH REDWATER	SHAW 49	673.80	294.05
C572070049	HINTON BIGLEG	112	2967.00	395.53
C572070051	PAUL BLACKREE	144	238.97	238.97
C572070055	ANNA BROWNBIRD	186	591.04	591.04
C572070058	SARAH GREASYDOG CRAZYMULE	246	973.19	883.26
C572070059	THERESA COOK	251	911.84	911.84
C572070062	JOHN DIVES BACKWARDS	265	1230.00	359.11
C572070068	PETER FIRSTCROW	318	300.00	300.00
C572070069	EUGENE FISHER	322	425.00	425.00
C572070074	NELLIE WHITEFROG FLYING	349	3368.30	1964.79
C572070076	NELLIE GRAY	367	3926.00	641.38
C572070080	HUBERT HOLLOWBREAST	438	7540.00	987.57
C572070083	CHARLES KILLSNIGHT	480	1098.00	1098.00
C572070086	STANLEY LAMEWOMAN	524	1438.00	726.33
C572070090	VICTOR LITTLECHIEF	569	1731.00	1731.00
C572070091	DORA LITTLEHAWK	576	3636.25	2752.60
C572070095	WILLIAM LITTLEWOLF	642	4803.00	201.76
C572070096	MAY WOMANLEGGINS LITTLEWOLF	643	164.00	164.00
C572070098	NELSON MEDICINE BIRD	711	2634.00	2060.97
C572070104	DANIEL OLDBULL	760	5636.80	1206.89
C572070105	NORA WALKSEASYPINE	779	2554.00	1532.14
C572070106	NORA BIGNOSEPINE	785	1612.00	1022.06
C572070107	ALBERT MAGPIE	699	2812.00	2264.03
C572070108	NANCY SLEEPINGWOLF REDBEADS	805	1778.70	669.99
C572070111	JAMES REDFOX	834	780.80	771.62
C572070112	HENRY REDNECK	840	3163.00	3063.75
C572070114	LUCY REDNOSE	852	822.72	822.72
C572070127	HENRY WILLIAM SWEETMEDICINE	1152	654.00	633.71
C572070130	FANNIE HAPIROBE TEETH	1192	827.00	827.00
C572070131	BESSIE TWIN	1211	3965.00	784.76
C572070133	LENORA ARAPAHOECHIEF TWOBIRDS	1215	5198.00	1278.50
C572070143	DALLAS WOLFBLACK	1347	2431.00	804.59
C572070147	ROBERT YELLOWNOSE	1434	1440.80	951.94

BILLINGS AREA: ESTATES DELETED FROM FIRST LIST

C512010031	C512010063	C512010069	C512011431	C512011439	C512011441
C512011442	C512011476	C512011488	C512011489	C512011490	C512011492
C512011493	C512011494	C512011495	C512011496	C512011497	C512011499
C512011500	C512011501	C512011503	C522020055	C522020057	C522020059
C522020061	C522020062	C522020063	C522020065	C522020081	C522020085
C522020088	C522020089	C552040105	C552040108	C562060054	C562060085
C562060096	C562060108	C562060109	C562060122	C562060123	C562060125
C562060135	C562060163	C562060169	C562060174	C572070040	C572070048
C572070050	C572070054	C572070056	C572070061	C572070063	C572070065
C572070071	C572070077	C572070078	C572070099	C572070100	C572070109
C572070119	C572070121	C572070125	C572070126	C572070128	C572070132
C572070139	C572070140	C572070144	C572070149		

MINNEAPOLIS AREA: ESTATES IDENTIFIED SINCE PUBLICATION OF FIRST LIST

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
F524090076	MAGGIE TUCKER	NA	1547.00	857.82
F534070242	RICHARD DAY	1577	912.50	912.50
F534070253	MAGGIE THOMPSON	585	0.00	100.00
F534081857	PENAY	4290	722.00	27.07
F534081858	NOW WAH KE GAH BOW E QUAY	1906	525.00	35.17

MINNEAPOLIS AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
F534040041	WM JOHNSON	37	983.10	150.87
F534050034	WM O. COFFEY	118	81.55	81.55
F534050035	RIGHT BONEY	83	10341.53	392.38
F534050040	MAISH KOW WAY WE DUNG	224	2955.82	740.13
F534050041	WISH E BAH KAH MIG OKE	424	1613.13	1613.13
F534050156	LOUISA W. WOOD	W003067	819.00	368.59
F534070229	PAISH KE WAY KE SHIG OKE	789	924.00	924.00
F534070240	MAGGIE MCCABE BURRING	732	2806.90	602.94
F534070244	MRS JOHN FINEDAY	979	4857.50	2365.71
F534070247	AY NE WAUSH	362	0.00	90.00
F534070248	JOHN WOOD	1612	6003.75	2210.26
F534070250	ROBERT A. BLAKELY	255	5130.34	272.92
F534070251	JOHN MINK	969	798.00	116.66
F534070254	MARY JANE RICE	4960	140.20	115.45
F534070256	QUAY QUAY CUB	1024	3414.00	2744.27
F534070257	MRS. CHARLES RABBIT	778	890.00	890.00
F534070258	MARY DRUMBEATER	721	1085.00	1085.00
F534070259	BOB MOSOMO	1046	905.00	100.00
F534070271	MARY SPRUCE FISHER	GP 194	4366.01	121.11
F534070272	MICHAEL FLATT	GP 234	8514.45	168.19
F534070274	THERESA MORRISON	GP 81	7083.40	365.91
F534070955	MRS. JOHN MINK	1230	574.00	252.15
F534080496	CHARLES CASSAWAY	2047	650.00	200.83
F554300088	MARY S. GREEN BRESETTE	132	651.50	470.25
F554310085	MARY HOMESKY LARSON BAKER	28	5701.00	265.00
F554360001	JOHN A. LAGREW	N5614	1128.75	162.21
F554390109	HENRY THUNDER	R3477	653.45	653.45

MINNEAPOLIS AREA: ESTATES DELETED FROM FIRST LIST

F534050033 F534050043 F534070231 F534070252 F534070266 F534070269
F534070273 F534080702 F534081856

PORTLAND AREA: ESTATES ON FIRST LIST, CORRECTED AND MODIFIED

ISSUE NO.	NAME OF DECEDENT	DECEDENT ID	$ ALLOWED	$ PAID
P061170035	JACK WARD	1406	79.11	79.11
P111240040	WYSOOKIE WYNOOKIE	2846	237.72	237.72

PORTLAND AREA: ESTATES DELETED FROM FIRST LIST

P061200012 P111240042 P111240044 P121020016

[FR Doc. 85-26871 Filed 11-12-85; 8:45 am]
BILLING CODE 4310-02-C

Bureau of Land Management

[CA 7040 WR, CA 7041 WR, CA 7043 WR, LA 0119534 WR, R 03517 WR]

California; Proposed Continuation of Withdrawals

September 12, 1985.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

Correction

In FR Doc. 85-22534 beginning on page 38221 in the issue of Friday, September 20, 1985, make the following corrections:

1. In the second column, the thirty-fourth line is corrected to read,

"W¼NE¼, S½S½SE¼NE¼, and".

2. In the second column, the twenty-sixth and twenty-seventh lines from the bottom are corrected to read as follows:

"County.

Public Land Order No. 3446 of September 23, 1964."

BILLING CODE 1505-01-M

Opening of Public Land; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Lands Open to Entry.

SUMMARY: The Federal Energy Regulatory Commission has cancelled its licenses and vacated the withdrawal of approximately 2,180 acres of public lands in Utah for transmission line Project No. 994. Effective June 24, 1985, at 10:00 am, the subject lands were opened to the operation of the public land laws and the mineral laws.

FOR FURTHER INFORMATION CONTACT: Nancy Bloyer, BLM, Utah State Office, 324 South State, Suite 301, Salt Lake City, Utah 84111-2303, 801-524-4036.

SUPPLEMENTARY INFORMATION: Notice is hereby given that pursuant to section 24 of the Federal Power Act of 1920, as amended (16 U.S.C. 818), the Federal Energy Regulatory Commission has vacated the withdrawal affecting certain public lands in Utah for Project 994. The withdrawal was described in Federal Power Commission letters of October 4, 1927, April 17, 1936, August 6, 1938, and December 13, 1940, to the General Land Office, and September 7, 1948, and September 9, 1952, to the Bureau of Land Management and covered approximately 2,180 acres within the following described sections:

Salt Lake Meridian, Utah

T. 12 S., R. 1 E., sec. 28.
T. 13 S., R. 1 W., secs. 7, 8, 9, 10, 18.
T. 13 S., R. 2 W., secs. 13, 22, 23, 27, 28, 29, 31.
T. 14 S., R. 2 W., secs. 5, 6.
T. 14 S., R. 3 W., secs. 12, 13, 14, 22, 23, 28.
T. 15 S., R. 3 W., secs. 5, 6.
T. 22 S., R. 3 W., secs. 30, 31.
T. 23 S., R. 3 W., secs. 19, 20, 21, 27, 28.
T. 28 S., R. 3 W., secs. 17, 18, 20, 29.
T. 29 S., R. 3 W., secs. 5, 8, 17, 20
T. 30 S., R. 3 W., secs. 5, 8, 17.
T. 21 S., R. 4 W., secs. 33, 34.
T. 22 S., R. 4 W., secs. 3, 10, 11, 13, 14, 24.
T. 23 S., R. 4 W., secs. 3, 10, 14, 15, 23, 24.
T. 28 S., R. 4 W., secs. 1, 11, 12, 13, 14, 17, 20, 21, 22, 23, 28, 29, 30.
T. 31 S., R. 4 W., secs. 8, 9, 17, 20, 29, 30, 31.
T. 25 S., R. 4½ W., secs. 35.
T. 26 S., R. 4½ W., secs. 9, 10, 16, 17, 18, 19.
T. 32 S., R. 4½ W., secs. 6, 7, 18.
T. 15 S., R. 5 W., secs. 13, 27, 28, 33.
T. 16 S., R. 5 W., secs. 5, 6, 7.
T. 25 S., R. 5 W., secs. 30, 31, 33.
T. 26 S., R. 5 W., secs. 9, 10, 13, 14, 15, 24, 25, 26, 34, 35.
T. 27 S., R. 5 W., secs. 4, 5, 6, 7.
T. 28 S., R. 5 W., secs. 25, 35.
T. 29 S., R. 5 W., secs. 3, 8, 9, 10, 17, 18, 19.
T. 32 S., R. 5 W., secs. 23, 24, 26, 27, 34.
T. 33 S., R. 5 W., secs. 3, 4, 9, 17, 20, 29, 30, 31.
T. 34 S., R. 5 W., secs. 6, 7, 17, 18, 19, 30.
T. 16 S., R. 6 W., secs. 12, 13, 14, 15, 20, 21, 22, 29.
T. 25 S., R. 6 W., secs. 33, 34
T. 26 S., R. 6 W., secs. 4, 5, 7, 8.
T. 27 S., R. 6 W., secs. 12, 13, 24, 25, 26, 35.
T. 28 S., R. 6 W., secs. 2, 10, 11, 15, 16, 21, 28, 29.
T. 29 S., R. 6 W., secs. 5, 6, 7, 17, 18, 20, 21, 23, 24, 26, 27, 38, 34.
T. 30 S., R. 6 W., secs. 4, 8, 9, 17, 18, 19.
T. 29 S., R. 7 W., secs. 13, 18.
T. 30 S., R. 7 W., secs. 24, 25, 26, 35.
T. 31 S., R. 7 W., secs. 3, 10, 15, 20, 21, 29, 30.
T. 29 S., R. 8 W., secs. 7, 8, 9, 10, 13, 14, 15.
T. 28 S., R. 9 W., secs. 19, 28, 29, 30, 33, 34.
T. 29 S., R. 9 W., secs. 3, 10, 11, 12, 15, 20, 29, 30, 31.
T. 30 S., R. 9 W., sec. 6.
T. 28 S., R. 10 W., secs. 8, 15, 23, 24.
T. 30 S., R. 10 W., sec. 1.
T. 27 S., R. 11 W., secs. 22, 27, 30, 31, 33, 34.
T. 28 S., R. 11 W., secs. 1, 3, 4, 12.
T. 27 S., R. 12 W., secs. 19, 20, 21, 22, 25, 26, 27.

At 10:00 a.m. on June 24, 1985, the public lands described above were opened to the operation of the public land laws, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications received at or prior to 10:00 a.m. on June 24, 1985, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

Dated: November 1, 1985.

Orval L. Hadley,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 85-26920 Filed 11-12-85; 8:45 am]

BILLING CODE 4310-DQ-M

[U-53701, U-54847]

Sale of Public Lands in Rich County, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action—Sale of Public Lands U-53701, U-54847.

SUMMARY: The following described land has been examined and identified as suitable for disposal under section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713), at no less than the appraised fair market value shown:

Tract identifier	Legal description	Acreage	Appraised value
U-53701	T. 9 N., R.6 E., SLM: Sec. 20, SE¼NE¼NE¼SW¼NE¼, NE¼SE¼NE¼SW¼NE¼	1.25	$300
U-54847	T. 9 N., R.6 E., SLM: Sec. 23, SE¼NE¼SE¼NE¼NW¼, SE¼NE¼SW¼SE¼NE¼NW¼, SE¼SW¼SW¼SE¼NE¼NW¼, SE¼SW¼SE¼NE¼NW¼, SE¼SE¼NE¼NW¼.	4.0625	$500

The above described land will be sold in order to dispose of lands which because of location and other characteristics are difficult and uneconomical to manage. The sale is consistent with the Bureau's planning system and the public interest will be served by offering these lands for sale.

The lands described are hereby segregated from appropriation under the public land laws, including the mining laws, pending disposition of this action.

The above described land will be sold at 10:00 a.m. on January 15, 1986, without competitive bidding at the Bureau of Land Management (BLM) Salt Lake District Office at 2370 South 2300 West, Salt Lake City, Utah. Tract U-53701 will be sold directly to Mr. Keith Cornia of Woodruff, Utah, and tract U-54947 will be sold directly to Mr. DeVerl Putnam of Woodruff, Utah. The appraised value as shown must be submitted or received by the Salt Lake District Office prior to or at the date and time shown above.

Payment may be made by the principal or his duly qualified agent.

Payment shall be by a certified check, postal money order, bank draft or cashier's check, made payable to the

Department of the Interior, BLM for the appraised value as shown above and shall be enclosed in a sealed envelope clearly marked "Payment for Public Land" and stating the serial number as shown above for the tract to be purchased.

The terms and conditions applicable to the sale are:

(1) The patent will contain a reservation for ditches and canals and be subject to all valid existing rights including rights-of-way U–048145 and U–035998 for State Highway 39.

(2) All minerals will be reserved to the United States including the right of ingress or egress for mineral development on tract U–54847. The minerals on tract U–53701 are not held by the United States and will not be a part of the sale.

For a period of 45 days from the date of this notice, interested parties may submit comments to the District Manager, BLM, 2370 South 2300 West, Salt Lake City, Utah 84119. Any adverse comments will be evaluated by the District Manager who may vacate or modify this realty action and issue a final determination. In the absence of any action by the State Director, this realty action will become the final determination of the Department of the Interior.

Dated: October 31, 1985.

Frank W. Snell,

Salt Lake District Manager.

[FR Doc. 85–26915 Filed 11–12–85; 8:45 am]

BILLING CODE 4310-DQ-M

Grand Junction District Grazing Advisory Board, Colorado; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting of Grand Junction District Grazing Advisory Board.

SUMMARY: Notice is hereby given in accordance with Pub. L. 92–463 that a meeting of the Grand Junction District Grazing Advisory Board will be held on Thursday, December 12, 1985. The meeting will convene at 9:00 a.m. in the conference room at the Bureau of Land Management Office, 764 Horizon Drive, Grand Junction, Colorado.

SUPPLEMENTARY INFORMATION: The agenda for the meeting will include (1) introduction of new members, (2) minutes of the previous meeting, (3) discussion of allotment management plan revisions in the Grand Junction Resource Area, (4) current status of project work, (5) discussion of pending Rangelands Legislation, (6) discussion of possible termination of authority for grazing advisory boards and effects on use of monies now returned for use by grazing advisory boards for range improvements, (7) discussion of East Desert Well, (8) proposed new advisory board projects, (9) public presentations, and (10) arrangements for the next meeting.

The meeting is open to the public. Interested persons may make oral statements to the Board between 3:00 and 3:30 p.m. or file written statements for the Board's consideration. Anyone wishing to make an oral statement must notify the District Manager, Bureau of Land Management, 764 Horizon Drive, Grand Junction, Colorado 81506, by December 9, 1985. Depending on the number or persons wishing to make oral statements, a per person time limit may be established by the District Manager.

Minutes of the board meeting will be maintained in the District Office and be available for public inspection and reproduction (during regular business hours) within thirty (30) days following the meeting.

Further information on the meeting may be obtained at the above address or by calling (303) 243–6552.

Dated: November 4, 1985.

Dick Freel,

Associate District Manager, Grand Junction District.

[FR Doc. 85–27043 Filed 11–12–85; 9:27 am]

BILLING CODE 4310-JB-M

Bureau of Reclamation

Westlands Water District's Long-Term Drainage Disposal Project Cancellation of Notice of Intent To Prepare a Joint Environmental Impact Report (EIR)/ Environmental Impact Statement (EIS)

The Bureau of Reclamation (Bureau), Department of the Interior, on August 20, 1985 (50 FR 33649) published a Notice of Intent to prepare a joint Environmental Impact Report (EIR/Environmental Impact Statement (EIS) in cooperation with the Wetlands Water District (WWD). This joint EIR/EIS would have addressed the impacts of various alternatives to provide a long-term solution to dispose of approximately 6,500–10,000 acre-feet of subsurface agricultural drainage water originating within the WWD. This action was proposed following the Secretary of the Interior's March 15, 1985 decision to initiate the process of closing Kesterson Reservoir, Merced County, California as a disposal facility for agricultural drainage. Subsequently, on April 3, 1985, the Department of the Interior and WWD entered into an agreement which requires the cessation of agricultural drainage water discharge into the San Luis Drain north of Bass Avenue and into the Kesterson Reservoir by June 30, 1986.

Originally the WWD proposed to use the San Luis Drain south of Bass Avenue to transport subsurface agricultural drainage water to a site within WWD for storage and evaporation/treatment. The San Luis Drain is a Federal facility operated by the Bureau. Its use by the WWD, as proposed, would have required the Bureau's permission. The WWD recently changed their proposed action. It now proposes to utilize on-farm management, water cycling and, if necessary, drainage system plugging to comply with the April 3, 1985 agreement with the Department of the Interior. The WWD is no longer planning to utilize the San Luis Drain for its long-term drainage disposal project; therefore, no action by the Bureau is required and a joint EIR/EIS will not be prepared. The WWD is preparing an EIR addressing alternative actions on its part. The Bureau will now consider the entire San Luis Drain in the Kesterson cleanup closure EIS process.

Further information may be obtained from Alan Solbert of the Environmental Compliance Branch, Bureau of Reclamation, 2800 Cottage Way, Sacramento, CA 95825–1898; telephone (916) 978–5130.

Dated: November 7, 1985.

B.H. Spillers,

Acting Commissioner.

[FR Doc. 85–26948 Filed 11–12–85; 8:45 am]

BILLING CODE 4310-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 84–44]

Stephen Granet Rosen, D.D.S.; Revocation of Registration

On September 28, 1984, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued to Stephen Granet Rosen, D.D.S. of 777 N.E. 79th Street, Miami Beach, Florida 33138 (Respondent) an order to show cause proposing to revoke his DEA Certificate of Registration AR0153065. The proposed action as predicated on Respondent's conviction of felony offenses relating to a controlled substance on November 23, 1983, in the Circuit Court for the Eleventh Judicial Circuit of Florida. By letter dated October 30, 1984, Respondent's counsel

requested a hearing on the issues raised by the order to show cause.

On November 19, 1984, the Deputy Assistant Administrator issued to Respondent a second order to show cause proposing that Respondent's DEA registration be revoked for reason that such registration is inconsistent with the public interest. 21 U.S.C. 823(f) and 824(a)(4). It was stipulated that both grounds might be addressed at the hearing, but Government counsel requested that the public interest issue in the second show cause order be considered by the Administrative Law Judge only if the criminal conviction ground stated in the first show cause order was found to be without merit.

The hearing in this matter was held in Miami, Florida on November 28, 1984. Administrative Law Judge Francis L. Young presided. On July 2, 1985, Judge Young issued his opinion and recommended ruling, findings of fact, conclusions of law and decision. No exceptions were filed and, on August 1, 1985, Judge Young transmitted the record of these proceedings to the Administrator. The Administrator has considered this record in its entirety and, pursuant to 21 CFR 1316.67, hereby issues his final order in this matter, based upon findings of fact and conclusions of law as hereinafter set forth.

The Administrative Law Judge found that during 1983, Respondent planned a jewel robbery at a luxury apartment complex. Respondent enlisted two confederates in this scheme, one of whom was a police informant who revealed the plan to the Metro-Dade County Police. The jewel robbery was never executed. However, during a meeting to discuss details of the proposed jewel robbery, Respondent discussed the price and quality of methaqualone powder as though he were trafficking, or willing to traffic, in that substance.

In or about December 1982, Respondent accidentally discovered that his mercedes car keys also fit another Mercedes automobile in an apartment garage. Respondent secreted a confederate in the back of Respondent's car and drove the confederate into the garage so that he could steal the other car. The plan was successful and the car was eventually sold. Respondent and the confederate divided the proceds.

The confederate was arrested and began cooperating with the police. He told police officers that he had obtained a number of prescriptions for controlled substances from Respondent. These prescriptions were written in fictitious names and were not for any legitimate medical purpose. The confederate was outfitted with a listening device. He approached Respondent and asked him if Respondent would be interested in purchasing a quantity of allegedly stolen methaqualone tablets at a good price. Respondent expressed his interest, and delivery of the methaqualone tablets was made to Respondent on September 27, 1982. He was thereupon arrested.

Respondent was charged with a number of offenses. In one case he was charged with trafficking in cocaine and with possession of cocaine with intent to sell it. On October 20, 1983, following a non-jury trial in that case, Respondent was found guilty of the lesser included offense of possession of cocaine, a felony offense under Florida Statutes sections 893.13. The State's Attorney also filed informations charging Respondent with Grand Theft in the Second Degree relating to the theft of the Mercedes automobile and with unlawful and felonious possession of methaqualone, relating to the attempted purchase of bags of methaqualone from the cooperating individual. On October 27, 1983, Respondent entered pleas of *nolo contendere* to these two charges. No charges were formally filed with respect to the plot to commit the jewel robbery or with respect to a Percodan prescription which Respondent had written for his confederate, again in a false name and for no legitimate purpose.

On November 23, 1983, the Circuit Court, pursuant to a provision of Florida law, ordered that adjudication of guilt be withheld in each of the three cases in which Respondent had been found guilty or had entered a plea of *nolo contendere* and that Respondent be placed on probation for five years. Special terms of the probation were that Respondent enter an in-house residential program for substance abusers and that he pay a fine.

The Administrative Law Judge found that Respondent was diagnosed as a "chemically dependent person." Beginning shortly after November 23, 1983, Respondent entered several in-house treatment facilities. Respondent is currently attending Alcoholics Anonymous and Narcotics Anonymous, three to four times a week.

On October 26, 1984, the Florida Board of Dentistry entered a Final Order regarding Respondent's license to practice dentistry. Dr. Rosen was assessed an administrative fine of $2,000; his dental license was suspended for one year, but the suspension was stayed; and his license was placed on probation for five years. It was further ordered that Respondent shall not dispense or administer Schedule II controlled substances. This provision will be reviewed after one year to see if it should be modified or deleted.

Respondent contends that he has not been "convicted" as required by 21 U.S.C. 824(a)(2). The Administrative Law Judge found that the criminal proceedings against Respondent in the Florida State Court were terminated pursuant to section 948.01 of the Florida Code. This section provides that a defendant in a criminal case, after a plea of guilty or *nolo contendere*, or after a finding of guilt by judge or jury, may be placed on probation for a period of time subject to certain conditions, and that "the court, in its discretion, may . . . withhold the adjudication of guilt . . ." Respondent argued that since the court withheld "adjudication of guilt," he has not been "convicted."

In *Delaney* v. *State*, 190 So. 2d 579 (Fla. 1966), the Florida Supreme Court stated that the purpose of section 948.01 was to permit rehabilitation for one who had committed a crime while avoiding the stigma of a formal judgment of conviction. However, the holding in this case was that a probation order without a formal adjudication, pursuant to section 948.01, is a "final judgment" of the trial court subject to review on appeal.

Additionally, several federal cases have interpreted section 948.01 of the Florida Code and have concluded that upon the entry of a plea of guilty, a defendant is considered convicted. See, *United States* v. *Hartsfield*, 387 F. Supp. 16 (U.S.D.C., M.D. Fla. 1975); *United States* v. *Cook*, 10 M.J. 138 (U.S. Ct. Mil. App. 1981); See also, *Boykin* v. *Alabama*, 395 U.S. 238, 89 S.Ct. 1709 (1969).

DEA has consistently held that a registrant is convicted of a controlled substance-related felony if there is a judgment of guilt, plea of guilty or *nolo contendere* or some other indication that he has been found guilty of a controlled substance-related felony. See *Faunce Drug Store*, Docket No. 82-3, 47 FR 30122 (1982) and cases cited therein. The propriety of DEA's relying on a conviction based on a *nolo contendere* plea in actions such as this has been specifically upheld by the Federal appellate courts in *Sokoloff* v. *Saxbe*, 501 F.2d 571 (2nd Cir. 1974) and *Noell* v. *Bensinger*, 586 F.2d 554 (5th Cir. 1978).

The Administrative Law Judge concluded that Respondent Rosen was "convicted" in the Florida criminal court on charges of possession of cocaine and possession of methaqualone within the meaning of the phrase "convicted of a felony" in 21 U.S.C. 824(a)(2).

Since Judge Young concluded that Respondent was "convicted" and that

there is a lawful basis for revoking Respondent's registration on that ground, 21 U.S.C. 824(a)(2), he did not consider the merits of the second order to show cause, based on the recently enacted "public interest" ground. See Pub. L. 98-473, Title II, §§ 511-513 (Oct. 12, 1984).

Respondent further argued that neither of the drug-related felonies with which he was charged (and "convicted") was directly related to his practice of dentistry and the exercise of his privileges under his DEA registration. While this is true, DEA has consistently held that conviction of a controlled substance-related felony, even though unrelated to a registrant's professional practice, requires the same sanction as one which is so related. See, *Tilman J. Bently, D.O.*, Docket No. 82-22, 49 FR 35049 (1984); *Dennis Howard Harris, M.D.*, Docket No. 84-19, 49 FR 39930 (1984); *Raymond H. Wood, D.D.S.*, Docket No. 82-32, 48 FR 48727 (1983).

Respondent further contended that his wrongful conduct resulted from his drug addiction from which he is now recovering. Judge Young noted that there might be a causal connection between Respondent's extraordinary criminal conduct and his admitted drug addiction. However, the Administrative Law Judge was not persuaded that Respondent has progressed in his "recovery" program to the point that he should be entrusted with a DEA registration and the responsibilities pertaining thereto.

Judge Young concluded that Respondent's conduct was so bizarre for a person in his position, and so out of keeping with his station and responsibilities, that a much more persuasive showing of his ability to control himself should be made before Respondent is granted a DEA registration. The Administrative Law Judge recommended that Respondent's registration be revoked.

The Administrator, after considering the record in its entirety, hereby adopts the recommended ruling, findings of fact, conclusions of law and decision of the Administrative Law Judge.

According, having concluded that there is a lawful basis for the revocation of Respondent's registration and having further concluded that under the facts and circumstances presented in this case the registration should be revoked, the Administrator of the Drug Enforcement Administration, pursuant to the power vested in him by 21 U.S.C. 824 and 28 CFR 0.100(b), hereby orders that DEA Certificate of Registration AR0153065, previously issued to Stephen Granet Rosen, D.D.S., be, and it hereby is, revoked.

Dated: November 6, 1985.

John C. Lawn,

Administrator.

[FR Doc. 85-26950 Filed 11-12-85; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 85-36]

Crosstowns Drugs, Nashville, TN; Hearing

Notice is hereby given that on June 17, 1985, the Drug Enforcement Administration, Department of Justice, issued to Lonnie Edward Maze, d/b/a Crosstowns Drugs, an Order To Show Cause as to why the Drug Enforcement Administration should not revoke its DEA Certificate of Registration AC9530987, and deny any pending applications for registration as a pharmacy under 21 U.S.C. 823(f).

Thirty days having elapsed since the said Order To Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 9:30 a.m. on Thursday, November 21, 1985, in Courtroom No. 874, U.S. District Court, U.S. Courthouse, 801 Broadway, Nashville, Tennessee.

Dated: November 6, 1985.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 85-26951 Filed 11-12-85; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 85-47]

Medicine Shoppe, Donelson, TN; Hearing

Notice is hereby given that on September 4, 1985, the Drug Enforcement Administration, Department of Justice, issued to the Medicine Shoppe, an Order To Show Cause as to why the Drug Enforcement Administration should not deny its application for registration executed on August 13, 1985, for registration as a retail pharmacy under 21 U.S.C. 823(f).

Thirty days having elapsed since the said Order To Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 9:30 a.m. on Thursday, November 19, 1985, in Courtroom No. 874, U.S. District Court, U.S. Courthouse, 801 Broadway, Nashville, Tennessee.

Dated: November 6, 1985.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 26952 Filed 11-12-85; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 85-40]

Skelton's Pavilion Pharmacy, Nashville, TN; Hearing

Notice is hereby given that on July 22, 1985, the Drug Enforcement Administration, Department of Justice, issued to James A. Skelton, d/b/a Skelton's Pavilion Pharmacy, an Order To Show Cause and Immediate Suspension of Registration affording Respondent the opportunity to show cause as to why the Drug Enforcement Administration should not revoke Certificate of Registration AS1883861 previously issued to Skelton's Pavilion Pharmacy.

Thirty days having lapsed since the said Order To Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 9:30 a.m. on Wednesday, November 20, 1985, in Courtroom No. 874, U.S. District Court, U.S. Courthouse, 801 Broadway, Nashville, Tennessee.

Dated: November 6, 1985.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 85-26953 Filed 11-12-85; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 85-12]

Walker Lanier Whaley, M.D., Jacksonville FL; Hearing

Notice is hereby given that on January 15, 1985, the Drug Enforcement Administration, Department of Justice, issued to Walker Lanier Whaley, M.D., an Order To Show Cause as to why the Drug Enforcement Administration should not revoke his DEA Certificate of Registration, AW6639681, as a practitioner under 21 U.S.C. 823(f).

Thirty days having elasped since the said Order To Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter is rescheduled to begin at 10:00 a.m. on tuesday, November 26, 1985, in Courtroom No. 10, Room 309,

U.S. Claims Court, 717 Madison Place, NW., Washington, D.C.

Dated: November 6, 1985.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 85-26954 Filed 11-12-85; 8:45 am]

BILLING CODE 4410-09-M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards, Subcommittee on Emergency Core Cooling Systems; Meeting

The ACRS Subcommittee on Emergency Core Cooling Systems will hold a meeting on November 22, 1985, Room 1046, at 1717 H Street, NW., Washington, DC.

To the extent practical the meeting will be open to public attendance. However, portions of the meeting will be closed to permit discussion of material that would not otherwise be available to the Subcommittee regarding the FY 1987 budget.

The agenda for the subject meeting shall be as follows:

*Friday, November 22, 1985—8:30 a.m. until the conclusion of business.*The Subcommittee will review selected portions of the NRC thermal hydraulic research program for the ACRS Report to Congress on the FY 1987 budget.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Paul Boehnert (telephone 202/634-3267) between 8:15 a.m. and 5:00 p.m. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: November 6, 1985.

Morton W. Libarkin, *Assistant, Executive Director for Project Review.*

[FR Doc. 85-26966 Filed 11-12-85; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-352 OL, 50-353 OL]

Philadelphia Electric Co. (Limerick Generating Station, Units 1 and 2); Oral Argument

Notice is hereby given that, in accordance with the Appeal Board's order of October 24, 1985, oral argument on the appeals of the Graterford inmates and Air and Water Pollution Patrol (AWPP) from the Licensing Board's July 22, 1985, fourth partial initial decision (LBP-85-25) will be heard at *2:00 p.m. on Wednesday, December 4, 1985, in the NRC Public Hearing Room, Fifth Floor, East-West Towers Building, 4350 East-West Highway, Bethesda, Maryland.*

Dated: November 6, 1985.

For The Appeal Board.

C. Jean Shoemaker,

Secretary to the Appeal Board.

[FR Doc. 26967 Filed 11-12-85; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-348 and 50-364]

Alabama Power Co.; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from the requirements of Appendix R to 10 CFR Part 50 to Alabama Power Company, (the licensee), for the Joseph M. Farley Nuclear Unit Nos. 1 and 2 located near the City of Dothan, Alabama.

Environmental Assessment

Identification of Proposed Action: The exemption would permit alternatives to the technical requirements of Appendix R concerning certain specifically identified fire areas in Farley Unit No. 2 and areas shared with Unit No. 1.

The exemption is responsive to the licensee's application for exemptions dated March 13, 1985, as supplemented by letters dated June 26, and July 19, 1985.

The Need for the Proposed Action: The proposed exemption is needed because the features described in the licensee's requests regarding the existing fire protection at the plant for these items are the most practical means for meeting the intent of Appendix R and literal compliance would not significantly enhance the fire protection capability.

Environmental Impacts of the Proposed Action: The proposed exemption and modifications to be made will provide a degree of fire protection that is equivalent to that required by Appendix R for the affected areas of the plant such that there is no increase in the risk of fires at this facility. Consequently, the probability of fires has not been increased and the post-fire radiological releases will not be greater than previously determined nor does the proposed exemption otherwise affect radiological plant effluents. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with this proposed exemption.

With regard to potential non-radiological impacts, the proposed exemption involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect non-radiological plant effluents and has no other environmental impact. Therefore, the Commission concludes that there are no significant non-radiological environmental impacts associated with the proposed exemption.

Alternative Use of Resources: This action involves no use of resources not previously considered in the Final Environmental Statement (construction permit and operating license) for the Joseph M. Farley Nuclear Plant, Units 1 and 2.

Agencies and Persons Consulted: The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed exemption.

Based upon the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the application for exemptions dated March 13, 1985, and supplements dated June 26 and July 19,

1985, which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the Local Public Document Room, located at the George S. Houston Memorial Library, 212 W. Burdeshaw Street, Dothan, Alabama.

Dated at Bethesda, Maryland, this 4th day of November 1985.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Acting Assistant Director for Operating Reactors, Division of Licensing.

[FR Doc. 85-26957 Filed 11-12-85; 8:45 am]

BILLING CODE 7590-01-M

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the Office of Management and Budget review of information collection.

SUMMARY: The Nuclear Regulatory Commission has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission: new, revision or extension: Extension.

2. The title of the information collection: Certificate of Disposition of Materials.

3. The form number if applicable: NRC Form 314.

4. How often the collection is required: Once, upon termination of the license.

5. Who will be required or asked to report: Persons holding NRC licenses to possess and use radioactive materials, who do not wish to renew those licenses.

6. An estimate of the number of responses: 200.

7. An estimate of the total number of hours needed to complete the requirement or request: 100.

8. An indication of whether section 3504(h), Pub. L. 96-511 applies: Not applicable.

9. Abstract: NRC Form 314 informs NRC whether a terminating licensee has properly transferred or disposed of materials procured under the license and constitutes part of the basis for NRC's determination that the facility has been cleared of radioactive materials before the facility is released for unrestricted use.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 1717 H Street, NW., Washington, DC 20555.

Comments and questions should be directed to the OMB reviewer, Jefferson B. Hill, (202) 395-7340.

The NRC Clearance Officer is R. Stephen Scott, (301) 492-8585.

Dated at Bethesda, Maryland, this First day of November 1985.

For the Nuclear Regulatory Commission

Patricia G. Norry,

Director, Office of Administration.

[FR Doc. 85-26958 Filed 11-12-85; 8:45 am]

BILLING CODE 7590-01-M

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the (OMB) review of information collection.

SUMMARY: The Nuclear Regulatory Commission has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission, new, revision or extension: Extension.

2. Title of the information collection: 10 CFR Part 21 Reporting of Defects and Noncompliance.

3. The form number if applicable: Not applicable.

4. How often the collection is required: On occasion.

5. Who will be required or asked to report: NRC licensees and directors or responsible officers of non-licensees that supply components to licensed facilities or activities.

6. An estimate of the number of responses: 450 annually.

7. An estimate of the total number of hours needed to complete the requirements or request: 72,600 annually.

8. An indication of whetehr section 3504(h), Pub. L. 96-511 applies: Not applicable.

9. Abstract: Part 21, the Commissions regulation implementing Section 206 of the Energy Reorganization Act of 1974, results in reports describing defects in basic components at licensed nuclear facilities. These reports are reviewed by the NRC staff to determine whether the reported defects or failures to comply are potential generic safety issues. In addition to identifying areas for specific plant inspection followup, these reports of potential safety problems have resulted in NRC bulletns and many information notices contributing to the improved safety of the nuclear industry.

Copies of the submittal may be inspected or obtained for a fee from NRC Public Document Room, 1717 H Street, NW., Washington, DC 20555.

Comments and questions should be directed to the OMB reviewer Jefferson B. Hill, (202) 395-7340.

NRC Clearance Officer is R. Stephen Scott, (301) 492-8585.

Dated at Bethesda, Maryland, this 5th day of November 1985.

For the Nuclear Regulatory Commission.

Patricia G. Norry,

Director, Office of Administration.

[FR Doc. 85-26959 Filed 11-12-85; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-244]

Rochester Gas and Electric Corp.; Consideration of Issuance of Amendment to Facility Operating License and Opportunity for Prior Hearing

The United States Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-18 issued to Rochester Gas and Electric Corporation (the licensee), for the R.E. Ginna Nuclear Power Plant, located in Wayne County, New York. The amendment would modify the Technical Specifications (TS) to (1) Increase the spent fuel pool (SFP) storage capacity by authorizing storage of consolidated fuel canisters in the existing SFP and imposing restrictions on the storage of the consolidated fuel canisters in the SFP, and (2) modify the current prohibition on the use of the Auxiliary Building crane over the SFP to authorize use of the crane to move consolidated fuel canisters, in accordance with the licensee's application for amendment dated February 27, 1985, as supplemented June 10, June 26, and July 11, 1985.

Prior to issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and Commission's regulations

By December 13, 1985, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance

with the Commission's Rules of Practice for Domestic Licensing Proceedings in 10 CFR Part 2. If a request for a hearing for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order. Since this is the first application filed after the enactment of the Nuclear Waste Policy Act of 1982 (42 U.S.C. Sec. 10154) for a license amendment to expand onsite spent fuel capacity by the use of consolidation of fuel canisters, the special provisions allowing for the hybrid hearing process of that section do not apply to this application.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularly the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under construction. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene shall be filed with the Secretary of the Commission, United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may by delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner or representative for the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700) The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Mr. John A. Zwolinski: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 and to Harry H. Voigt, Esquire, Le Boeuf, Lamb, Lieby and MacRae, 1333 New Hampshire Ave., N.W., Suite 1100, Washington, D.C. 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated February 27, 1985, as supplemented June 10, June 26, and July 11, 1985, which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555 and at the Rochester Public Library, 115 South Avenue, Rochester, New York 14610.

Dated at Bethesda, Maryland, this 8th day of November 1985.

For the Nuclear Regulatory Commission.

John A. Zwolinski,

Chief, Operating Reactors, Branch No. 5, Division of Licensing.

[FR Doc. 85-27066 Filed 11-12-85; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

Proposed Transmittal Memorandum No. 1, Rescission of OMB Circular No. A-49, "Use of Management and Operating Contracts"

AGENCY: Office of Management and Budget, Office of Federal Procurement Policy.

ACTION: Notice of proposed rescission and request for comments.

SUMMARY: This notice provides interested parties with a proposed transmittal memorandum which would rescind OMB Circular No. A-49, "Use of Management and Operating Contracts" and establishes the requisite comment period before final publication.

FOR FURTHER INFORMATION CONTACT: Mr. Robert C. Bienvenue, Office of Federal Procurement Policy, (202) 395-6810.

SUPPLEMENTARY INFORMATION: OMB Circular No. A-49, February 25, 1959, established general criteria to assist Executive agencies in developing policies for the use of management and operating contracts. Management and operating contracts are used to administer research and development establishments; to administer and operate Government-owned or leased industrial facilities; or to operate such personal or professional services as are authorized by law. This category of contracts has limited applicability in the Executive agencies.

The policy in the Circular is restated in the Federal Acquistion Regulation, Subpart 17.6. As the environment for use of management and operating contracts has changed, contracting policies have reflected those changes. Additionally, where management and operating contracts are used as the funding vehicle for Federal Contract Research Centers, Federally-Funded Research and Development Centers, and/or Federal Laboratories, new policies have been issued to provide guidance in these unique situations, i.e., OFPP Policy Letter 84-1, "Federally Funded Research and Development Centers," dated April 4, 1984.

After review of these and other policies affecting management and operating contracts, OFPP has determined that adequate guidance on the use of management and operating contracts is provided in more recently updated regulations and guidance. Under these circumstances, Circular No. A–49 is no longer necessary and should be rescinded.

Comments

Agencies and other interested parties are invited to comment on this proposed rescission letter. Comments should include reference to this notice and be sent to: Mr. Robert C. Bienvenue, Office of Federal Procurement Policy, OMB, Room 9013, 726 Jackson Place, NW, Washington, DC 20503. Comments must be received 60 days from the date of this notice.

Dated: November 4, 1985.

William E. Mathis,

Acting Administrator

Office of Management and Budget

[Circular No. A–49; Transmittal Memorandum No. 1; Proposed]

To: The Heads of Executive Departments and Establishments

Subject: Use of Management and Operating Contracts

Office of Management and Budget Circular No. 49 is hereby rescinded. Policy and guidance affecting the use of management and operating contracts is found in the Federal Acquisition Regulation, Subpart 17.6, and in other related regulations and directives.

James C. Miller III,

Director.

[FR Doc. 85–26972 Filed 11–12–85; 8:45 am]

BILLING CODE 3110–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Extension of Deadline for Requests To Testify at November 18, 1985 Hearing on Possible U.S. Actions in Japan Leather and Leather Footwear Cases and Conversion of TSUS Item Description

SUMMARY: The Office of the United States Trade Representative has decided to extend the November 11, 1985 deadline for filing requests to testify at the November 18, 1985 hearing on possible leather and leather footwear cases announced in the Federal Register on November 1, 1985 (50 FR 45686). The deadline for filing requests to testify has been extended to noon November 12, 1985.

Additionally, the following correction and addition should be made in Part 4 of the Federal Register.

TSUS Item No.	Description
533.20–533.39	Articles chiefly used for preparing, serving or storing food or beverages, or food and beverage ingredients, of fine-grained earthenware (except provided for in item 553.15) or of fine-grained stoneware.
706.05	Flatgoods, of leather other than reptile leather.

J. Christine Bliss,

Associate General Counsel.

[FR Doc. 85–26946 Filed 11–12–85; 8:45 am]

BILLING CODE 3190–01–M

SECURITIES AND EXCHANGE COMMISSION

Forms Under Review by Office of Management and Budget

Agency Clearance Officer: Kenneth A. Fogash, (202) 272–2142.

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of Consumer Affairs and Information Services, 450 Fifth Street, NW., Washington, DC 20549.

Extension

Rule 2a19–1 [17 CFR 270.2a19–1]

File No. 270–294

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission has submitted for extension of OMB approval Rule 2a19–1 under the Investment Company Act of 1940, certain investment company directors not considered interested persons.

Comments should be submitted to OMB Desk Officer: Sheri Fox, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503.

John Wheeler,

Secretary.

November 5, 1985.

[FR Doc. 85–25701 Filed 11–12–85; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–22598; SR–NASD–85–17]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc., Order Approving Proposed Rule Change

The National Association of Securities Dealers, Inc. ("NASD"), on June 25, 1985, submitted copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, to amend section (i) of the Rules of Practice and Procedure for the automated interface between the Intermarket Trading System ("ITS") and the Computer Assisted Execution System ("CAES"),[1] pursuant to the provisions of Article III, section 37 of the NASD's Rules of Fair Practice. The amendment establishes specific procedures in regard to locked and crossed markets that have evolved through the operational experience and mutual agreement of the ITS Participants. The amendment provides for, among other things, a complaint and rectification procedure for the party whose quotation is locked or crossed which obligates the locking or crossing party to promptly ship stock or unlock the market, as directed.

Notice of the proposed rule change was given in Securities Exchange Act Release No. 22237, published in the Federal Register (50 FR 29290, July 18, 1985). No comments on the proposed rule change were received.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of sections 11A and 15A and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority. 17 CFR 200.30–3(a)(12).

Dated: November 6, 1985.

John Wheeler,

Secretary.

[FR Doc. 84–26975 Filed 11–12–84; 8:45 am]

BILLING CODE 8010–01–M

[1] CAES is an enhancement to the NASD's Automated Quotation ("NASDAQ") System that links over-the-counter ("OTC") market makers and that provides an order routing and execution capability. The ITS-CAES interface is a computer link between the exchange and OTC markets operated by the NASD and seven national securities exchanges. Presently, only Rule 19c–3 securities, which are listed securities that are not subject to exchange off-board trading restrictions, may be traded through that interface.

[Release No. 34-22594; File No. SR-Phlx-85-23]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Notice of Proposed Rule Change Relating to Exchange Governance

November 1, 1985.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on October 22, 1985, the Philadelphia Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") proposes to amend several of its rules relating to corporate governance. Italics indicate material proposed to be added; brackets indicate material proposed to be deleted.

Annual Meeting

Sec. 3-2. An annual meeting of the members shall be held in each calendar year on the second Monday in March. At such annual meeting there shall be elected by ballot the following officials: A Chairman of the Board of Governors for the term of two years if his term is then expiring or his office is then vacant; two Vice Chairmen of the Board of Governors for terms of one year each [: and commencing with the annual meeting in 1981 seven Broker Governors and one Public Governor for the term of three years] *, 3 On-Floor Governors, 3 Off-Floor Governors and 1 At-Large Governor.* At each annual meeting there shall also be elected by ballot *On-Floor, Off-Floor or At-Large* governors to fill vacancies in the Board of Governors which may have occurred during the preceding year. [In any election of members of the Board of Governors, due regard shall be given to the provisions of the By-Laws with respect to the composition of the Board of Governors of the Corporation.]

Nominating Committee

Sec. 3-5(a) The Nominating Committee shall submit nominations for the positions of Chairman, Vice Chairman [and] *, On-floor, Off-Floor, and At-Large* Governor on the Board of Governors of the Corporation to be filled at the annual elections of the Corporation. The Chairman of the Board and the President of the Corporation shall not be ex-officio members of the Nominating Committee.

Sec. 3-5 (b), (c), and (d) No change.

Open Meeting of Committee—Recommendations—Notice

Sec. 3-6 (a) and (b) No change.

Sec. 3-6(c) The Nominating Committee shall nominate no person for a position on the Board of Governors [, exclusive of Chairman of the Board,] if one or more other persons [affiliated] *associated* with his member organization would be serving an unexpired term or terms on the Board upon the commencement of his term of office in the event of his election. The Nominating Committee shall nominate no more than one person [affiliated] *associated* with the same member organization in any election to fill vacancies on the Board of Governors [exclusive of the office of Chairman of the Board,] and regardless of the number of vacancies to be filled. *For purposes of Article 3 of these By-Laws, the term "person associated with the same member organization" means a person who is a partner, officer, director, or substantial shareholder (ten per cent or more) of the same member organization or of a member organization that directly controls, is controlled by or is under common control with such member organization. Participation in a joint account does not per se constitute an association with the same member organization.*

Sec. 3-6(d) A candidate who is not an incumbent officer or governor on the Board of Governors may run for only one of the offices of Chairman, Vice Chairman, *On-Floor, Off-Floor* or *At-Large* Governor in any election. An incumbent officer or governor need not resign to be a candidate for one other office but in the event of his election he shall serve in only one of the aforesaid offices at the same time.

Sec. 3-6(e) *In the event of a merger, consolidation or other acquisition, which results in persons serving on the board who are associated with the same member organization, as defined in By-Law Sec. 3-6(c), all but one such person shall notify the Chairman of the Board of their resignation by the first day of January preceding the next annual election in order that the Nominating Committee may fill the vacancy created thereby. Such resignation shall become effective no later than the expiration of the term of the outgoing class of governors.*

Sec. 3-6(f) *If the minimum number of governors required in either of the categories of on-floor governor or off-floor governor is not maintained because of any governor's change in occupational category or member organization association, such governor shall notify the Chairman of the Board of his resignation by the first day of January preceding the next annual election in order that the Nominating Committee may fill the vacancy created thereby. Such resignation shall become effective no later than the expiration of the term of the outgoing class of governors.*

Sec. 3-6[(e)]*g* No change.

Members May File Independent Nominations-Requirements

Sec. 3-7. (a) Independent nominations for the positions of Chairman, Vice Chairman, *On-Floor, Off-Floor,* and *At-Large* Governor on the Board of Governors may be made by a written petition filed with the Secretary of the Corporation in a sealed envelope within two weeks after the posting of the report of the Nominating Committee. No such nomination shall be valid unless it is signed by not less than ten members. No member shall endorse more than one nominee; provided, however, that thirty members may, by petition, propose an entire ticket, or any portion thereof, for the vacancies on the Board of Governors to be filled at the ensuing election. *A person is not eligible for an independent nomination for a position on the Board of Governors if one or more persons associated with his member organization, as defined in By-Law Sec. 3-6(c), would be serving an unexpired term or terms on the Board upon the commencement of his term of office in the event of his election. No more than one person associated with the same member organization, as defined in Sec. 3-6(c), shall be certified by the Election Committee for independent nomination to a position on the Board of Governors. In the event more than one such nomination is received, the Election Committee shall not certify any such candidates. A person who has previously accepted nomination by the nominating Committee for one category of Governor (e.g. On-Floor, Off-Floor, or At-large Governor) is not eligible to qualify as an independent candidate in any category. There may be no independent nominations of incumbent governors whose terms do not expire following the next election.* The Elections Committee and the Secretary of the Corporation shall open such envelopes, and if found eligible for election, the persons nominated by petition conforming with the foregoing provisions shall be deemed nominees for such positions on

the Board of Governors. The names of all nominees for membership on the Board of Governors, whose nominations conform with By-Law requirements, shall be sent to all members of the Corporation by the Secretary as promptly after the third Monday of February as is reasonably possible. The order of nominees' names on notices and on the ballot shall be determined through a drawing by lot conducted by the Elections Committee.

Sec. 3-7(b) No change.

Sec. 3-7(c) The ballot containing the names of the candidates nominated for membership on the Board of Governors shall indicate by appropriate designation whether the nominee is s member of the Corporation or is a non-member of the Corporation who is a general partner or *executive* officer (*vice president or above*) of a member organization of this Corporation[, or is a representative of the public unaffiliated with the Corporation or any broker or dealer in securities]. In the event that there are more nominations of persons in the [classification composed of members of the Corporation or general partners or officers of member organizations (Broker Governors), or of persons in the classification composed of representatives of the public (Public Governors)] *categories of Chairman, Vice Chairman, and On-Floor, Off-Floor and At-Large Governor* than there are vacancies on the Board of Governors which may be filled by such persons, the number of such persons who may be elected to membership on the Board of Governors *in each category* shall also be indicated on the ballot.

Death, Withdrawal or Disqualification of Nominee

Sec. 3-8. In the case of the death, withdrawal or disqualification at any time in advance of an annual election of a nominee proposed by the Nominating Committee or by petition, for one of the positions on the Board of Governors of the Corporation to be filled at such annual election *other than the offices of Chairman and Vice-Chairman of the Board of Governors*, the election for such position shall proceed at the appointed date, notwithstanding such death, withdrawal or disqualification. In the event that by reason of such death, withdrawal or disqualification there are fewer candidates for such office of Governor of the Corporation than there are vacancies to be filled, the Board of Governors, at a meeting held subsequent to such annual election may elect a person to the office left vacant under such circumstances, the person to be elected to serve until the third Wednesday of March following the next annual election of the Corporation, or may, in its discretion, direct that a special election of the Exchange be held to fill such vacancy.

In case of the death, withdrawal or disqualification at any time in advance of an annual election of a nominee proposed for the office of the Chairman of the Board of Governors or a Vice-Chairman of the Board of Governors, the election for any such office as to which a nominee has so died, withdrawn or became disqualified shall not proceed at the appointed date, but the Board of Governors shall call a special election of the Corporation for such office. If such special election shall be directed, the Board shall determine the procedure for the same, including the procedure for the making and receiving of further nominations.

Votes Required to Elect

Sec. 3-9. [In any election for members of the Board of Governors if either the number of Broker Governors or the number of Public Governors which are nominated exceeds the vacancies which may be filled by such persons, votes cast for such persons who fail of election because of lack of vacancies which may be filled by them shall be ignored in determining the standing of the other candidates for membership on the Board.]

The nominees receiving at an election for membership on the Board of Governors the highest number of votes for the offices [to be filled] *for which they were nominated* shall be declared elected to those offices. In the case of a tie, the names of the nominees involved shall be referred to the Board of Governors which shall make the selection.

If governors are to be elected to fill vacancies differing in length, the largest vote shall elect for the longest term.

Board of Governors—Number—Composition

Sec. 4-1. The management of the business and affairs of the Corporation shall be vested in a Board [of Directors which shall be designated as the "Board of Governors"] *of Governors*. The Board of Governors shall be composed of the Chairman of the Board of Governors; two Vice Chairman of the Board of Governors; the President of the Corporation; and [the number of governors] *not more than 26 Governors* as hereafter provided. [From the effective date of the By-Law amendment increasing the number of Public Governors and decreasing the number of Broker Governors, until the third Wednesday of March in 1981 there shall continue to be twenty-four (24) Broker Governors and one (1) Public Governor; on and after the third Wednesday of March in 1981 until the third Wednesday of March in 1982 there shall be twenty-three (23) Broker Governors and two (2) Public Governors; on and after the third Wednesday of March in 1982 until the third Wednesday of March in 1983 there shall be twenty-two (22) Broker Governors and three (3) Public Governors; on the third Wednesday of March 1983 and thereafter there shall be twenty-one (21) Broker Governors and three (3) Public Governors.] *At least 9 of the 26 Governors shall be members who are primarily engaged in business on the Exchange Floor or general partners, executive officers (vice president and above) or members associated with member organizations primarily engaged in business on the Exchange Floor (On-Floor Governors); at least 9 of the 26 Governors shall be general partners, executive officers (vice president or above), or members associated with member organizations which conduct a non-member public customer business and shall individually not be primarily engaged in business activities on the Exchange Floor (Off-Floor Governors); 3 Governors shall be persons who qualify either as on-floor or off-floor governors (At-Large Governors); and 3 Governors shall be appointed by the Board, who shall be representatives of the public unaffiliated with the Exchange or any broker or dealer in securities (Public Governors).* In addition, the immediate past Chairman of the Board of Governors, upon the expiration of the term to which he was elected, shall be an ex-officio member of the Board of Governors with vote for a term of one year and the past President of the Corporation, retired as President as of May 1, 1981, shall serve at the pleasure of the Board of Governors as an ex officio member thereof with vote. [Broker Governors shall be members of the Corporation or general partners or officers of a member organization. Public Governors shall be representatives of the Public unaffiliated with the Corporation or any broker or dealer in securities.]

Election of Chairman and Vice-Chairman of the Board

Sec. 4-2. The Chairman of the Board of Governors and the Vice Chairmen of the Board, to be eligible for nomination, must each have been a member of the Corporation or a general partner or an *executive* officer (*vice president or above*) of a member organization for a cumulative period of at least three years *immediately* preceding the day his term

of office commences. *Any lapses in such continuous membership or association which total thirty days or less will not disqualify a candidate who has otherwise been a member or so associated for three years immediately preceding the day his term of office commences.* In addition, one Vice Chairman and the organization with which he is [affiliated] *associated* shall conduct primarily a [business with public securities customers] *non-member public customer business;* and the other Vice Chairman shall spend the major portion of his time on [either or both trading floors] *the trading floor* of the Exchange or be [affiliated] *associated* with an organization [a substantial] *the primary* portion of whose business is conducted on [either or both of] such trading floor[s].

The Chairman of the Board and the Vice Chairmen of the Board shall each be elected by the membership of the Corporation at the annual meeting. The Chairman shall be elected for a term of two years [or] *and* until his successor is elected and qualifies. Each Vice Chairman shall be elected for a term of one year [or] *and* until his successor is elected and qualifies.

After serving two consecutive two-year terms to whch he has been elected by the membership, the Chairman shall be ineligible for further service in such office until after an interval of at least one year.

After serving four consecutive one-year terms to which he has been elected by the membership, a Vice Chairman shall be ineligible for further service in such office until after an interval of at least one year.

[Terms served prior to the third Wednesday of March in 1981 by the Chairman and Vice Chairmen shall not be counted in computing their length of service.]

Classification

Sec. 4–3. The *On-Floor, Off-Floor and At-Large* Governors, and *Appointed* Public Governors shall be divided into three classes. *Commencing in 1986,* [O]*one* such class shall be [elected by the membership of the Corporation] *constituted by election and appointment* each year to serve for three years [or] *and* until their successors are elected and qualify.

[The classes whose terms expire on the third Wednesdays of March in 1981, 1982, and 1983 respectively shall each have eight Broker Governors. The class whose term expires in 1983 shall have one public governor.]

Notwithstanding the provisions of By-Law 4–1 and the first paragraph of this by-law, [T]*the classes* [to be elected at the annual meetings of members commencing in 1981 and in succeeding years, and whose terms expire on the third Wednesday of March in 1984 and on such day in succeeding years, shall each be composed of seven Broker Governors and one Public Governor] *whose terms expire in 1986, 1987 and 1988 shall remain as currently constituted until their terms expire.*

Elections Committee

Sec. 10–11(a). The Elections Committee shall have supervision over the balloting at all elections of the Corporation and at all meetings thereof to consider proposed amendments to the By-Laws or other matters. It shall administer the By-Laws and rules governing voting at all elections and meetings of the Corporation and shall make or recommend for adoption such rules as it may deem necessary for the conduct of such voting. As provided in Section 3–7 of the By-Laws, the Committee shall receive nominations for positions to be filled at the annual meeting of the Corporation.

Appeals

Sec. 11–1(a). An appeal to the Board of Governors from a decision of a Standing Committee, other than the Admissions Committee, the Arbitration Committee, the Business Conduct Committe or the Disciplinary Review Committee, may be taken by a member or member organization interested therein by filing with the Secretary of the Corporation a written notice of appeal within ten days after the decision has been rendered. A member of a Standing Committee, other than the Admissions, Arbitration, Business Conduct Committee, Elections Committee or Disciplinary Review Committee, taking part in the hearing of a matter, may by filing written notice with the Secretary of the Corporation within ten days after a decision has been made thereon, appeal therefrom to the Board of Governors. There shall be no appeal from a decision of the Committee on Admissions, except as provided in Section 17–5 of Article XVII. There shall be no appeal from a decision of the Arbitration Committee in any arbitration proceeding or from a decision of the Disciplinary Review Committee in a disciplinary action or proceeding.

(b) Notwithstanding the foregoing, any appeal from a decision of the Nominating Committee or the Elections Committee regarding the eligibility of any candidate for election to the Board of Governors by the membership shall be heard by a special committee of the Board of Governors composed of not less than a majority of all governors who are not then candidates for office on the Board. An affected candidate or interested party may appeal by filing a written notice thereof with the Secretary of the Corporation within seven days after a decision as to his eligibility. Said notice shall also state the reasons for his appeal and the relief requested. He may appear before the special committee and present arguments concerning his eligibility. An appropriate record shall be kept. The decision of the special committee shall be final.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for the Proposed Rule Change

The proposed changes to PHLX by-laws would provide for 3 classes of governors who will serve for terms of 3 years. Each class will be composed of 4 categories of governors: 3 on-floor; 3 off-floor; 1 at-large; and 1 public. Except for public governor, all categories of governors will be elected. Public governors will be appointed by the Board. The new categories will apply to each successive outgoing class of governors; incumbent governors will not be affected until their terms expire. Also, the restrictions against dual associations among governors have been broadened to include independent candidates and the Chairman of the Board. Except for restrictions regarding dual associations, which now apply equally to independent and slated candidates, the by-law changes do not affect the right of a member to run as an independent candidate.

A brief summary of some of the particular drafting changes follows:

In By-law 3–6(c), the term "affiliated" is changed to "associated" and the term is defined for purposes of determining what type of associations will operate to disqualify more than one person from

serving on the Board of Governors. By-law 3–6(e) provides for the resignation of a governor(s) who becomes associated with the same member organization as another governor through merger or consolidation of their respective member organizations. Similarly, By-law 3–6(f) provides for resignation of a governor who has a change in occupation category or member organization which causes the number of governors required in one of those categories to fall below the minimum number set in By-law 4–1.

The prohibition against multiple associations among governors is broadened to include independent nominees in By-law 3–7(a) and the Chairman of the Board in By-law 3–6(c). Also, there may be no independent nominations of incumbent governors whose terms are not expiring.

For purposes of qualifying to be a candidate for governor, an "executive officer of a member organization" is defined as a person with the title of vice-president and above.

The first paragraph of By-law 3–9(a) concerning is deleted as surplusage; this material is covered in the remaining paragraphs of this By-law.

By-law –1 sets out the new composition of the Board and defines the categories of on-floor, off-floor, at-large and public governor.

Clarifying changes are made to By-law 4–2 in order to conform it to prior sections and to excuse a lapse of thirty days of otherwise continuous memberships from making a candidate ineligible for nomination as Chairman of the Board.

The amendments to By-law 4–3 provide for integration of the new governance rules over the next three years as each successive class of governors expires.

New By-law 11–1(a) provides for a special appeal procedure for decisions of Nominating and Election Committees regarding eligibility of a candidate for election to the Board of Governors.

The proposed rule change which generally provides for a more balanced representation among off-floor and on-floor members and the appointment of public governors is consistent with Section 6(b)(3) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competiton.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or,

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20459. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by December 4, 1985.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

John Wheeler,

Secretary.

[FR Doc. 85–26973 Filed 11–12–85; 8:45 am]

BILLING CODE 8010–01–M

[Release No. IC–14788; File No. 812–6105]

Commerzbank Aktiengesellschaft; Notice of Application

November 6, 1985.

Notice is hereby given that Commerzbank Aktiengesellschaft ("Bank"), c/o David J. Schwartz, Esq., Debevoise & Plimpton, 875 Third Avenue, New York, N.Y. 10022, and Commerzbank U.S. Finance, Inc. ("Subsidiary," and together with Bank, "Applicants"), c/o Ulrike Ahlers, Esq., Commerzbank Aktiengesellschaft, 55 Broad Street, New York, New York 10004, filed an application on May 2, 1985, and an amendment thereto on October 3, 1985, pursuant to section 6(c) of the Investment Company Act of 1940 ("Act"), for an order of the Commission exempting Applicants from all provisions of the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations made therein, which are summarized below, and to the Act for a statement of the relevant provisions thereof.

The Applicants state that the Bank, a banking corporation organized under the laws of the Federal Republic of Germany, with approximately 140,000 shareholders is one of the "Big Three" German banks. As of December 31, 1984, the Bank had total assets of U.S. $38,940,778,000 and total loans amounted to U.S. $28,671,682,000, representing 73.6% of total assets. According to the application, the Bank offers, directly or through its subsidiaries, a wide range of commercial, retail and investment banking services in Germany as well as internationally.

The application states that the Subsidiary is a Delaware corporation, all of whose capital stock, when issued, will be owned by the Bank. The Subsidiary represents that there has been, and undertakes that in the future there will be, no public offering of its capital stock or any other of its equity securities. The Applicants state that the Subsidiary's sole business will be the issuance and selling of its commercial paper notes and loaning the net proceeds from the sale thereof to the Bank and issuing and selling the Subsidiary's other debt securities and advancing or loaning the net proceeds from the sale thereof to the Bank. The Applicants state that substantially all of the Subsidiary's assets will consist of the Subsidiary's right to receive repayments from the Bank of the Bank's indebtedness arising by reason of the

loans and other advances so made by the Subsidiary.

The application states that the Bank is subject to extensive supervision and regulation by German banking authorities which is comparable in many respects to the supervision of United States commercial banks. The Federal Banking Supervisory Authority and the Federal Banking Law under which the Authority regulates, impose the following requirements, among others, on German banks: each bank must maintain adequate equity capital and liquidity; large loans must be restricted in relation to a bank's equity capital; and periodic reports must be filed with regard to minimum reserve, liquidity, equity capital, and foreign exchange limitations. The German Central Bank assists, and cooperates with the Federal Banking Supervisory Authority, with regard to the supervision of banking activities in the Federal Republic of Germany.

According to the application, the Bank proposes to issue short-term negotiable promissory notes of the type generally referred to as commercial paper in the United States in order to provide an alternative source of supply of United States dollars. The Subsidiary proposes to issue and sell in the United States commercial paper notes (which together with the commercial paper notes issued by the Bank are hereinafter referred to as the "Commercial Paper Notes").

It is stated that the Commercial Paper Notes will be issued in minimum denominations of U.S. $100,000 and the other terms thereof, including their maturity and manner of offering, will be such as to qualify them for exemption from registeration under the Securities Act of 1933, as amended (the "Securities Act"), provided by section 3(a)(3) or section 4(2) of the Securities Act. The Applicants state that they will not issue or sell any Commercial Paper Notes until having received an opinion of its legal counsel in the United States that the Commercial Paper Notes would be entitled to such an exemption. The Applicants do not request Commission review or approval of such opinion letter. The Applicants further represent that, prior to their issuance, the Commercial Paper Notes will have received one of the three highest investment grade ratings from at least one nationally recognized statistical rating organization and that the Applicants' United States counsel shall have certified that such rating shall have been received, provided, however, that no such rating shall be required to be obtained if in the opinion of such United States counsel, after having taken into account for the purpose of such opinion the doctrine of "intergration" referred to in Rule 502 under the Securities Act and various releases and no-action letters made public by the Commission, an exemption from registration is available under section 4(2) of the Securities Act.

The application states that the Commercial Paper Notes will be issued and sold by the Applicants through one or more commercial paper dealers in the United States to investors. It is represented that the Commercial Paper Notes will not be advertised or otherwise offered for sale to the general public, but instead will be sold to institutional investors and other entities and individuals who normally purchase commercial paper. The Applicants also state that they undertake to ensure that each offeree of the Commercial Paper Notes will receive prior to purchase a memorandum which briefly describes the Applicants' business and includes the Bank's most recent publicly available annual financial statements, which shall have been audited in a manner customarily done for the Bank by German auditors, together with a description of the material differences, if any, between accounting principles applied in the preparation of such financial statements and generally accepted accounting principles applied by United States banks. The Applicants state that such memorandum will be at least as comprehensive as those customarily used in commercial paper offerings in the United States and will be updated periodically to reflect material changes in the Applicants' financial status. Applicants consent to any order granting the relief requested being expressly conditioned on the foregoing undertaking

The Applicants state that in the event that the Commercial Paper Notes are issued by the Subsidiary rather than by the Bank directly, the Bank will unconditionally guarantee the Commercial Paper Notes. The Bank will expressly consent to the enforcement of such obligation directly by the holders of the Commercial Paper Notes or by the issuing and paying agent for the Commercial Paper Notes, which will be a major commercial bank, on behalf of such holders. The Bank's obligations in respect of its direct liabilities to holders of Commercial Paper Notes issued by it and its liabilites to the Subsidiary, including its liabilities in respect of the Subsidiary's obligations under the Commercial Paper Notes, will rank *pari passu* and equally with all deposit liabilities and other unsecured, unsubordinated indebtedness of the Bank and superior to any subordinated indebtness of the Bank and to claims of holders of its capital stock. The Bank states that it will expressly accept the jurisdiction of any State or Federal court in the City of New York, and will authorize an agent in the City of New York to accept service of process in any action based upon Commercial Paper Notes issued or supported by it or its obligations to the Subsidiary. Such consent to jurisdiction and such appointment of an authorized agent to accept service of process will be irrevocable until all amounts due and to become due in respect of any Commercial Paper Notes have been paid by the Bank or the Subsidiary.

The Applicants state that they may, from time to time, offer debt securities other than the Commercial Paper Notes in the United States. The proceeds of any such debt securities would, in the case of debt securities issued by the Subsidiary, be loaned or advanced to the Bank. The obligations of the Subsidiary in respect of any such debt securities issued by it would be supported by the Bank's unconditional guarantee. The Applicants undertake that, prior to their issuance, any further issue of the Applicants' debt securities other than the Commercial Paper Notes will have received one of the three highest investment grade ratings from at least one nationally recognized statistical rating organization and that the Applicants' United States counsel shall have certified that the rating was received. However, no such rating shall be required to be obtained with respect to an issue of the Applicant's debt securities other than the Commercial Paper Notes if, in the opinion of United States counsel to the Applicants, such counsel having taken into account for the purpose thereof the doctrine of "integration" referred to in Rule 502 under the Securities Act and various releases and non-action letters made public by the Commission, an exemption from registration is available for the issue pursuant to subsection 4(2) of the Securities Act.

The Applicants further undertake to ensure that any such future offering of such debt securities in the United States will be done on the basis of disclosure documents which will be no less comprehensive than is customary for U.S. offerings of similar debt securities. The Applicants undertake to ensure that any such disclosure documents will be provided to each offeree who has indicated an interest in the securities so offered prior to any sale of such securities to such offeree. The Bank states that it will, in connection with any future offering of its or the

Subsidiary's debt securities other than the Commercial Paper notes in the United States, expressly accept the jurisdiction of any State or Federal court in the City of New York, and will authorize an agent in the City of New York to accept service of process in any action based upon such debt securities issued or supported by it. Such consent to jurisdiction and such appointment of an authorized agent to accept service of process will be irrevocable until all amounts due and to become due in respect of any such debt securities have been paid by the Bank or the Subsidiary.

It is claimed that, because compliance with the Act would conflict with the Bank's commercial banking practices, the Bank would be effectively precluded from selling securities in the United States if it were required to register as an investment company. The Bank asserts that it is a major commercial bank subject to extensive regulation by German and U.S. banking authorities and as such is significantly different from the type of institutions that Congress intended the Act to regulate. The Applicants contend that the same rationale for exempting the Bank applies equally to the Subsidiary since the obligations of the Subsidiary will in effect be obligations of the Bank and since the Subsidiary's sole business will be to issue and sell debt securities and loan the net proceeds of the sale thereof to the Bank.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than December 2, 1985, at 5:30 p.m., do so by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, DC 20549. A copy of the request should be served personally or by mail upon Applicants at the addresses stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

John Wheeler,

Secretary.

[FR Doc. 85-26974 Filed 11-12-85; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

FAA Approval of Noise Compatibility Program; Seattle-Tacoma International, Seattle, Washington

AGENCY: Federal Aviation Administration, DOT.

ACTION: The Federal Aviation Administration (FAA) announced its findings on the noise compatibility program submitted by the Port of Seattle under the provisions of Title I of the Aviation Safety and Noise Abatement Act (ASNA) of 1979 (Pub. L. 96-193) and 14 CFR Part 150. These findings are made in recognition of the description of Federal and non-Federal responsibilities in Senate Report No. 96-52 (1980). On April 11, 1985, the FAA determined that the noise exposure maps submitted by the Port of Seattle under Part 150 were in compliance with applicable requirements. On October 4, 1985, the Administrator approved the Seattle-Tacoma International Airport noise compatibility program.

EFFECTIVE DATE: The effective date of the FAA's approval of the Seattle-Tacoma International Airport noise compatibility program is October 4, 1985.

FOR FURTHER INFORMATION CONTACT: Dennis G. Ossenkop; Federal Aviation Administration; Northwest Mountain Region; Airports division, ANM-611; 17900 Pacific Highway South; C-68968; Seattle, Washington 98168. Documents reflecting this FAA action may be obtained from the same individual.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise compatibility program for Seattle-Tacoma International Airport, effective October 4, 1985.

Under section 104(a) of the Aviation Safety and Noise Abatement Act (ASNA) of 1979, an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the noise exposure maps. The Act requires such a program to be developed in consultation with interested and affected parties including the state, local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with FAR Part 150 is a local program, not a Federal program. The FAA does not substitute its judgement for that of the airport proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in Part 150 and the Aviation Safety and Noise Abatement Act of 1979, and is limited to the following determinations:

The noise compatibility program was developed in accordance with the provisions and procedures of FAR Part 150;

Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government.

Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the Navigable Airspace and Air Traffic Control Systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in FAR Part 150, § 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA under the Airport and Airway Improvement Act of 1982. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Seattle, Washington.

The Port of Seattle submitted to the FAA on February 8, 1985, the noise exposure maps, descriptions, and other documentation produced during the noise campatibility planning study conducted at Seattle-Tacoma International Airport. The Seattle-

Tacoma International Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on April 11, 1985. Notice of this determination was published in the **Federal Register** on April 24, 1985.

The Seattle-Tacoma International Airport noise compatibility study contains a proposed noise compatibility program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in section 104(b) of the Act. The FAA began its review of the program on April 11, 1985, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained 15 proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The overall program, therefore, was approved by the Administrator effective October 4, 1985.

Outright approval was granted for 14 specific program elements and part of the 15th. Approved program elements relate to both on-airport and off-airport actions. On-airport actions include use of navigational aids to reduce flight track drift, establishment of a Noise Abatement Office, and on-airport operational alternatives related to future siting of buildings and taxiing. Off-airport elements include property acquisition, transaction assistance, noise insulation, navigation easements, and preventive land use planning and policies.

Part of one program element relating to possible regulation of training activity was disapproved pending submission to the FAA of additional details to permit an informed analysis under section 104(b) of the ASNA Act. This disapproval does not reflect FAA opposition to the noise mitigation objectives of the proposal or of the concept on which it is based. Rather, as described above, the ASNA Act contemplates approval or disapproval within the 180-day review period. Lacking adequate detail for a proper evaluation, the FAA has disapproved this action. This does not foreclose additional FAA review if additional information is submitted by the airport operator.

These determinations are set forth in detail in a Record of Approval endorsed by the Administrator on October 4, 1985. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the Port of Seattle Field Office-Noise Remedy Programs, 253 South 152nd Street, Seattle, Washington.

Issued in Seattle, Washington, on October 31, 1985.

Charles R. Foster,

Director, Northwest Mountain Region.

[FR Doc. 85-26895 Filed 11-12-85; 8:45 am]

BILLING CODE 4910-13-M

VETERANS ADMINISTRATION

Agency Forms Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document contains revisions and extensions and lists the following information: (1) The department or staff office issuing the form, (2) the title of the form, (3) the agency form number, if applicable, (4) how often the form must be filled out, (5) who will be required or asked to report, (6) an estimate of the number of responses, (7) an estimate of the total number of hours needed to fill out the form, and (8) an indication of whether section 3504(h) of Pub. L. 96-511 applies.

ADDRESSES: Copies of the forms and supporting documents may be obtained from Patricia Viers, Agency Clearance Officer (732), Veterans Administration, 810 Vermont Avenue NW, Washington, DC 20420, (202) 389-2146. Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Dick Eisinger, Office of Management and Budget, 726 Jackson Place NW, Washington, DC 20503, (202) 395-7316.)

DATES: Comments on the information collections should be directed to the OMB Desk Officer within 60 days of this notice.

Dated: November 5, 1985.

By direction of the Administrator:

Everett Alvarez, Jr.,

Deputy Administrator.

Revision

1. Department of Veterans Benefits.
2. Application for National Service Life Insurance.
3. VA Form 29-4364.
4. On occasion.
5. Individuals or households.
6. 4,300 responses.
7. 6,450 hours.
8. Not applicable.

Revision

1. Department of Veterans Benefits.
2. Veteran's Application for Education Benefits.
3. VA Form 22-1990.
4. On occasion.
5. Individuals or households.
6. 107,000 responses.
7. 79,827 hours.
8. Not applicable.

* * * * *

Extension

1. Department of Medicine and Surgery.
2. Agent Orange Registry Code Sheet.
3. VA Form 10-9009
4. Non-recurring.
5. Individuals or households.
6. 30,000 responses
7. 7,500 hours.
8. Not applicable.

Extension

1. Department of Medicine and Surgery.
2. Reapplication for Medical Benefits.
3. VA Form 10-10r.
4. On occasion.
5. Individuals or households.
6. 630,000 responses.
7. 50,400 hours.
8. Not applicable.

[FR Doc. 85-26969 Filed 11-12-85; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 50, No. 219
Wednesday, November 13, 1985

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

	Item
Federal Communications Commission	1
Federal Home Loan Bank Board	2
National Commission on Libraries and Information Science	3
Postal Service (Board of Governors)	4

1

FEDERAL COMMUNICATIONS COMMISSION

November 7, 1985.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, November 14, 1985, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, NW., Washington, DC.

Agenda, Item No., and Subject

Common Carrier—1—Title: Memorandum Opinion and Order on Further Reconsideration in the Cellular Lottery Proceeding. CC Docket No. 83-1096. Summary: The Commission will consider the petitions for reconsideration and/or clarification filed against the Memorandum Opinion and Order on Reconsideration (Cellular Lottery Reconsideration Order, 58 RR 2d 677) is this proceeding. The Commission will also consider the proposal of NewVector Communications, Inc. (See Public Notice CL-342, released August 8, 1985) regarding expediting the cellular licensing process.

Common Carrier—2—Title: Construction Period for New Cellular Communications Systems: Notice of Proposed Rulemaking. Summary: The Commission will consider adopting a Notice of Proposed Rulemaking to amend its rules to require a cellular permittee, in markets beyond the top-90, to begin initial operation of its cellular system within 12 months of the station authorization.

Common Carrier—3—Title: *GTE Sprint Communications Corporation, US Telecom, Inc., Allnet Communications Services, Inc., and United States Transmission Systems, Inc. Joint Petition for Expedited Rulemaking.* Summary: The FCC will consider the petitioners' request for the initiation of the rulemaking concerning the transition to competition in the long distance telephone market.

Mass Media—1—Title: Applications for consent to the transfer of control of the American Broadcasting Companies, Inc., licensee of various television, radio and broadcast auxiliary stations and common carrier authorizations, to Capital Cities Communications, Inc. and related transactions. Summary: The Commission will consider the applications to assign or transfer control of the broadcast licenses and common carrier authorizations held by the American Broadcasting Companies, Inc., directly or through subsidiaries. Also under consideration are various requests for permanent and limited waivers of the Commission's multiple ownership rules, Sections 73.3555 and 76.501.

Mass Media—2—Title: (1) Applications to assign the licenses of television stations WNEW-TV and W64AA (translator), New York, New York; KTTV, Los Angeles, California; KRLD-TV, Dallas, Texas; KRIV-TV, Houston, Texas; and WTTG, Washington, D.C., from Metromedia Radio & Television, Inc. to News America Incorporated (BALCT-850624KL-KP and BALCT-850624KR); (2) application to assign the license of station WFLD-TV, Chicago, Illinois, from WFLD Television, Inc. to News America Television Incorporated (BALCT-850624KQ); and (3) an application to assign the license of station WCVB-TV, Boston, Massachusetts, from Metromedia Radio & Television, Inc. to The Hearst Corporation (BALCT-850624KK). Summary: The Commission will consider News America Television Incorporated's (K. Rupert Murdoch) and The Hearst Corporation's applications to acquire-television stations WNEW-TV, KTTV, KRLD-TV, KRIV-TV, WTTG and WCVB-TV. K. Rupert Murdoch presently controls *The New York Post*, published in New York, New York, and *The Chicago Sun-Times*, published in Chicago, Illinois. Since § 73.3555(c)(3) of the Commission's Rules prohibits common-ownership of a daily newspaper and a television station, Murdoch has requested a two-year period within which to divest of the newspapers. The Commission will also consider petitions to deny filed by Sue Gottfried; the California Association of the Physically Handicapped, Inc., the National Coalition on Television Violence; the Media Access Project; the Washington Association for Television and Children; Metrowest Corporation, licensee of WPWR-TV, Aurora, Illinois, and Anthony R. Martin-Trigona.

Mass Media—3—Title: Amendment of Part 76 of the Commission's Rules Concerning Carriage of Television Broadcast Signals by Cable Television Systems. Summary: The Commission will consider initiating a combined inquiry and rule making proceeding to consider the matter of mandatory signal carriage rules for cable systems.

Mass Media—4—Title: The Use of Subcarrier Frequencies in the Aural Baseband of Television Transmitters (Docket No. 21323). Amendment of Parts 2, 73, and 76 of the Commission's Rules to Authorize Transmission of Teletext by TV Stations (BC Docket No. 81-741). Amendment of Parts 2, 73, and 76 of the Commission's Rules to Authorize the Offering of Data Transmission Services on the Vertical Blanking Interval by TV Stations (MM Docket No. 84-168). Amendment of Part 76 of the Commission's Rules and Regulations (§§ 76.59-76.63) with Respect to "Saturated" Cable Television Systems (Docket No. 21472). Amendment of Part 76 of the Commission's Rules and Regulations Concerning Cable Carriage of Significantly Viewed Signals (RM-3745). Petition for Inquiry into the Circumstances Justifying the Continuation or Deletion of §§ 76.55, 76.57, 76.59 and 76.61 of the Commission's Regulations.

Mass Media—5—Summary: The Commission will consider an action in several proceedings that relate to mandatory signal carriage rules for cable television systems. Title: Amendment of Part 73 of the Commission's Rules Concerning Equal Employment Opportunity in the Broadcast Radio and Television Services. Amendment of Broadcast Equal Employment Opportunity Rules and FCC Form 395. Summary: The Commission will consider initiating a rule making proceeding proposing changes to the equal employment opportunity (EEO) rules and reporting requirements for broadcast stations. The Commission also will consider whether to terminate the existing broadcast EEO proceeding (Docket No. 21474, RM-3397 and RM-3684).

Issued: November 6, 1985.

Federal Communications Commission.

William J. Tricarico.

Secretary.

[FR Doc. 85-27049 Filed 11-8-85; 1:57 pm]

BILLING CODE 6712-01-M

2

FEDERAL HOME LOAN BANK BOARD

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Vol. No. 50, Page No.—45705, Date Published—Friday, November 1, 1985.

PLACE: In the Board Room, 6th Floor, 1700 G St., NW., Washington, DC.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION: Ms. Gravlee (202-377-6679).

CHANGES IN THE MEETING: The following item has been withdrawn from the open meeting scheduled today at 10:00 a.m.

Industry Conflicts of Interest.

Jeff Sconyers,

Secretary.

No. 27, November 8, 1985.

[FR Doc. 85-26998 Filed 11-8-85; 10:53 am]

BILLING CODE 6730-01-M

3

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE

DATE AND TIME: December 2 and 3, 1985.

PLACE: Sheraton National Hotel, Arlington, Virginia.

STATUS:

December 2, 1985, 9:00 to 10:00 a.m. Closed. Sec. 1703.202 (2) and (6) of the Code of Federal Regulations, 45 CFR, Part 1703.

December 2, 10:00 a.m. to 5:00 p.m.

December 3, 9:00 a.m. to 5:00 p.m. Open.

MATTERS TO BE DISCUSSED:

Chairman's Report
Approval of Minutes
Discussion, The Role of Fees in Supporting Library and Information Services in Public and Academic Libraries
Executive Director's Report
—FY 1985 Final Program Report
—FY 1986 Progress Report
Discussion, Report from the Censorship Study
Committee Reports
—Ad Hoc Bicentennial
—Budget and Finance
—Public Affairs
Guest Speaker: Vartan Gregorian, President, New York Public Library
Old Business
New Business
Report, Preliminary Conference Design Group, Mr. William Asp, chairman

CONTACT: Toni Carbo Bearman, Executive Director, (202) 382-0840.

Toni Carbo Bearman,

Executive Director.

November 8, 1985.

[FR Doc 85-27013 Filed 11-8-85; 12:49 pm]

BILLING CODE 7527-01-M

4

POSTAL SERVICE (BOARD OF GOVERNORS)

Notice of Vote to Close Meeting.

At its meeting on November 4, 1985, the Board of Governors of the United States Postal Service unanimously voted to close to public observation its meeting scheduled for December 2, 1985, in Washington, DC. The meeting will involve consideration of a proposed filing with the Postal Rate Commission regarding third-class mail sacking requirements.

The meeting is expected to be attended by the following persons: Governors Camp, Griesemer, McKean, Peters, Ryan, Sullivan and Voss; Postmaster General Carlin; Deputy Postmaster General Strange; Secretary to the Board Harris; General Counsel Cox; and Counsel to the Governors Califano.

The Board of Governors has determined that, pursuant to section 552b(c)(3) of Title 5, United States Code, and § 7.3(c) of Title 39, Code of Federal Regulations, the meeting is exempt from the open meeting requirement of the Government in the Sunshine Act [5 U.S.C. 552b(b)], because it is likely to disclose information in connection with proceedings under chapter 36 of Title 39 (having to do with postal ratemaking, mail classification and changes in postal services), which is specifically exempted from disclosure by section 410(c)(4) of Title 39, United States Code. The Board also determined that pursuant to section 552b(c)(10) of Title 5, United States Code, and § 7.3(j) of Title 39, Code of Federal Regulations, the discussion is exempt because it is likely to specifically concern the participation of the Postal Service in a civil action or proceeding or the litigation of a particular case involving a determination on the record after opportunity for a hearing. The Board further determined that the public interest does not require that the Board's discussion of this matter be open to the public.

In accordance with section 552b(f)(1) of Title 5, United States Code, and § 7.6(a) of Title 39, Code of Federal Regulations, the General Counsel of the United States Postal Service has certified that in his opinion the meeting to be closed may properly be closed to public observation, pursuant to section 552b(c)(3) and (10) of Title 5 and section 410(c)(4) of Title 39, United States Code, and § 7.3(c) and (j) of Title 39, Code of Federal Regulations.

David F. Harris,

Secretary.

[FR Doc. 85-27085 Filed 11-8-85; 3:38 pm]

BILLING CODE 7710-12-M

Federal Register

Wednesday
November 13, 1985

Part II

Department of Transportation

Federal Aviation Administration

14 CFR Parts 21, 23, and 91
Shoulder Harnesses in Normal, Utility, and Acrobatic Category Airplanes; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21, 23, and 91

[Docket No. 23815; Amendment Nos. 21-58, 23-32, and 91-191]

Shoulder Harnesses in Normal, Utility, and Acrobatic Category Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The amendment to Part 23 of the Federal Aviation Regulations requires the installation of shoulder harnesses at all seats of normal, utility, and acrobatic category airplanes with a passenger seating configuration, excluding pilot seats, of nine or less, manufactured one year after the effective date of the amendment. The amendment to Part 91 of the Federal Aviation Regulations requires the pilot-in-command to brief passengers on how to fasten and unfasten their shoulder harnesses for both takeoff and landing in aircraft with installed shoulder harnesses. The amendment, also, requires each occupant to use a shoulder harness, if installed, for takeoff and landing. These amendments respond to the conclusions of an FAA Crashworthiness Study Report, to a petition for rulemaking from the General Aviation Manufacturers Association and to safety recommendations from the National Transportation Safety Board. These amendments will enhance the crashworthiness of small airplanes manufactured one year after the effective date of these amendments.

EFFECTIVE DATE: December 12, 1985.

FOR FURTHER INFORMATION CONTACT: J. Robert Ball, Regulations and Policy Office (ACE-110), Aircraft Certification Division, Central Region, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone (816) 374-5688.

SUPPLEMENTARY INFORMATION:

Regulatory History

These amendments are based upon a Notice of Proposed Rulemaking, Notice No. 85-11, published in the **Federal Register** (50 FR 19108; May 6, 1985). All comments received in response to Notice No. 85-11 were considered in adopting these amendments.

Background

Amendment 23-7 to Part 23 of the Federal Aviation Regulations (FAR), (34 FR 13078; August 13, 1969) upgraded many airworthiness standards for small airplanes. Section 23.785 was amended to require that each occupant must be protected from head injury by a safety belt and one of the following: (1) A shoulder harness to prevent the head from contacting any injurious object; (2) elimination of any injurious object within the striking radius of the head; or (3) an energy absorbing rest that would support the arms, shoulders, head, and spine.

On January 31, 1973, the FAA issued Notice No. 73-1 (38 FR 2985) proposing to amend Parts 23 and 91 of the FAR to require: (1) Shoulder harnesses for all occupants of newly certificated small airplanes; (2) shoulder harnesses for all occupants of small airplanes manufactured one year after the effective date of the amendments, regardless of the type certification basis of the airplane; and (3) all small airplanes in service with structural shoulder harness attachment provisions, to be equipped with shoulder harnesses within one year after the effective date of the amendment.

The final action on Notice No. 73-1, was supported by the following information: (1) Approximately 80,000 to 90,000 of the 13,000 U.S. registered small airplanes in service would have been required to add shoulder harnesses on the basis of existence of structural provisions; (2) the cost per seat for the installation of a shoulder harness would have varied from $20 to $200 for most airplanes, and installations made at the factory would mainly have been in the $20 to $40 per seat range; and (3) two percent of the then current airplanes would be equipped with shoulder harnesses, 50 percent of those shoulder harnesses would be used on a regular basis, and the increased availability of shoulder harnesses would have contributed significantly to occupant protection in an airplane accident.

As the final action on Notice No. 73-1, the FAA issued Amendment 23-19 to Part 23 and Amendment 91-139 to Part 91 (42 FR 30601; June 16, 1977). Amendment 23-19 requires the installation of shoulder harnesses for the front seats of all small airplanes for which an application for a type certificate is received after July 18, 1978. Amendment 91-139 requires the installation of shoulder harnesses for the front seats of small airplanes manufactured after July 18, 1978.

Section 23.785(j) was added to require, in part, that the cabin area surrounding each seat within striking distance of the occupant's head or torso be free of potentially injurious objects and, furthermore, if energy absorbing designs are used to meet this requirement, they must protect the occupant from serious injury when the occupant experiences the ultimate inertia forces set forth in § 23.561(b)(2).

The National Transportation Safety Board (NTSB) considered the new rules to be inadequate since the new requirements applied only to the front seats of airplanes and recommended installation of shoulder harnesses at all seats. In response to these safety recommendations, the FAA informed the NTSB that it was considering the feasibility of requiring the installation of shoulder harnesses at all seat locations and that the economic impact of the various options was being carefully assessed.

In December 1981, the FAA completed a benefit-to-cost analysis for the installation of shoulder harnesses in all general aviation airplanes. The analysis included nine alternatives for rulemaking action related to the installation and use of shoulder harnesses. The alternatives considered are cited as follows:

1. Amend Part 23 to require shoulder harnesses at all seats on newly certificated airplanes (extension of the current rule which requires shoulder harnesses at the front seats only).

Although this alternative would not have affected existing airplane designs, it would have imposed a future requirement for new airplanes regardless of whether the shoulder harness was used.

2. Amend Part 23 to require structural design provisions to accommodate the installation of shoulder harnesses at all rear seat locations on newly certificated airplanes.

This alternative would have provided the opportunity to install shoulder harnesses, at the owner's option, without the need for structural modification. This alternative would have not been applicable to airplanes being manufactured under the provisions of a current type certificate.

3. Amend Part 91 to require a shoulder harness at all seat locations on new airplane models; that is, those new airplane models manufactured under an amended type certificate, within a certain time period after the effective date of the amendment. Time periods of 1, 3, and 5 years were considered for this alternative.

This alternative was similar to alternative 1, except that the scope was broadened to include airplanes manufactured under an amended type certificate and a transition period was provided.

4. Amend Part 91 to require structural provisions to accommodate shoulder

harnesses at all seat locations on new airplane designs.

5. Amend Part 91 to require shoulder harnesses at all seat locations on newly manufactured airplanes after a specified date.

6. Amend Part 91 to require structural provisions to accommodate the installation of shoulder harnesses at all seat locations on all small airplanes within a specified time period.

7. Amend Part 91 to require the installation of shoulder harnesses at all seats on all small airplanes after a specified time,

All airplanes which did not have provisions for shoulder harnesses would have been required to be modified to meet the crashworthiness standards of Part 23.

8. Amend Part 91 to require structural provisions to accommodate the installation of shoulder harnesses at all seat locations on small airplanes prior to the time of registration.

This would have required sellers or buyers to modify the airplane before registration to the new owner.

9. Make no regulatory changes.

The FAA's Civil Aeromedical Institute (CAMI) completed a report in March 1982 entitled "Crashworthiness Studies: Cabin, Seat, Restraint, and Injury Findings in Selected General Aviation Accidents," Report No. FAA-AM-82-7. Numerous accidents were reviewed for features of crashworthiness and, in particular, for the injuries to the occupants in relation to the apparent severity of the impact and the performance of the cabin and occupant restraint systems.

In concluding the review, an estimate of the value of shoulder harnesses was made by the investigators. In the 47 accidents selected for further review, there were 136 persons involved. Eighty-seven (87) of these 136 were occupying a pilot or copilot seat, and it was estimated that 42 of the 49 occupants in rear seats would have had less severe injuries had shoulder harnesses been available and used. From this study, it is clear that shoulder harnesses enhance the crashworthiness of an airplane and reduce the possibility of serious or fatal injuries to occupants of other seats, in addition to those occupying the front seats.

A review of the 1981 Benefit-Cost Analysis and the CAMI Report indicated a varying positive benefit-to-cost ratio for alternatives 1, 2, and 7. Because alternative 7 is of such complexity and cost, and because some of the data upon which the 1981 study was based has changed, the FAA is conducting further study of this alternative before deciding if regulatory action is needed. Some of the factors which lead to the conclusion that further study was necessary are as follows:

1. The 1981 benefit-to-cost estimates the overall costs to be from $287 million to $328 million and more recent information indicates even higher costs.

2. The cost of shoulder harness installation can vary appreciably from one airplane to another. For example, the owner of an airplane manufactured without the attachment points for shoulder harnesses or whose airplane requires structural strengthening would have to bear significantly greater expense than an owner whose airplane only requires the installation of shoulder harnesses.

3. Rather than retrofit all seats, it may be more appropriate to retrofit only those seats where it can be done at reasonable cost or to retrofit only the front seats because these seats have a much higher occupancy rate than the rear seats and, correspondingly, the benefit-to-cost ratio will be significantly higher.

The FAA requested information from the public relating to the practicality of requiring the retrofitting of existing small airplanes with shoulder harnesses at all seats in Notice No. 85-11. In response to the request information, the FAA received little information either to support or to reject further rulemaking action on the retrofit issue.

Alternatives 1 and 2 were rejected because alternative 5, based upon new information and proposed in Notice No. 85-11, would provide much greater benefits than those in alternatives 1 and 2. In preparing the benefit-to-cost analysis for alternative 5 of the 1981 analysis, "Amend Part 91 to require the installation of shoulder harnesses at all seat locations on newly manufactured airplanes after a specified date.", it was assumed that the cost would include the design, installation of provisions for shoulder harnesses, and the shoulder harness. Further, the actual installation cost of shoulder harnesses, at each seat is now estimated at $150 to $250 per seat, because the attaching means for these shoulder harnesses will be provided in the affected airplane. Prior to developing Notice No. 85-11, the FAA was informed by the General Aviation Manufacturers Association, that after December 31, 1984, their newly manufactured small normal, utility, and acrobatic airplanes with a passenger seating configuration, excluding pilot seats, of nine or less, would have structural provisions incorporated and the member companies would be voluntarily installing shoulder harnesses where practical.

The GAMA manufacturers, which produce the majority of small airplanes, indicate that, except for airplanes purchased by Part 135 operators, they will, where practical, voluntarily provide structural provisions and install shoulder harnesses at all seat locations in these small airplanes. Accordingly, a review of the benefit-to-cost analysis has shown that alternative 5 would now have positive benefits relative to the estimated costs.

Consequently, the FAA concluded that the objective of alternative 5 would be more economically viable than alternatives 1 or 2. The substance of alternative 5 was proposed in Notice No. 85-11. For those small airplane manufacturers, which are not members of GAMA, the one year compliance period requiring the installation of shoulder harnesses at all seat positions on newly manufactured small airplanes was considered a reasonable length of time.

Discussion of Comments

In response to Notice No. 85-11, the FAA received comments from 19 interested persons. Most comments express agreement with the proposal.

One commenter states that, while favoring the proposal, amending § 23.785 addresses but one part of an overall absence of meaningful crashworthiness criteria within Part 23 of the FAR. This commenter contends the proposal is more form than substance until such time as the ultimate inertia forces set forth in § 23.561 are increased. The FAA does not agree with these remarks. Numerous studies by the FAA, NTSB, and others indicate that a significant improvement is made is small airplane crashworthiness by the installation and use of shoulder harnesses. While the Small Airplane Airworthiness Review Program (48 FR 4290, January 31, 1983), addresses the commenter's proposed increase in the ultimate static inertia forces of § 23.561(b)(2), a more appropriate course of action is to consider a dynamic testing requirement for seats and restraint systems simulating the survivable crash event and establishing criteria for occupant protection.

Two commenters contend that Technical Standard Order (TSO)-C22f, Safety belts, must be amended. One commenter states that TSO-C22f should be amended to require that the minimum standards for safety belt and shoulder harness systems be sufficient to restrain people equivalent to the 95th percentile man under foreseeable and survivable crash forces in a dynamic crash environment with due consideration for

the geometry of each particular installation. The commenter also states, that a 500 percent increase in the specified values to which restraint systems are presently required to be designed and manufactured under a TSO would have minimum economic impact. The second commenter provides detailed changes to be considered in amending TSO-C22f. The FAA has a program to consider dynamic testing of seats within Part 23 of the FAR and shoulder harnesses in this respect are considered a part of the airplane seats. In addition, the FAA has a program to amend TSO-C22f.

One commenter notes that the language used by the National Highway Traffic Safety Administration (NHTSA) and the FAA is substantially different in the area of passenger restraint systems. The commenter suggests that conformity of the FAA rulemaking to terminology now used throughout the passenger restraint industry (i.e., pelvic restraint; upper torso restraint) would impact favorably on the introduction of occupant restraint systems currently existing into the aviation industry in a form more closely aligned with the state-of-the-art. The FAA is aware of the differences in terminology between NHTSA regulations and those proposed by the FAA with regard to occupant restraint systems. The FAA considered the use of the term "upper torso restraint" instead of the term "shoulder harness" in the proposal. Since many of the Federal Aviation Regulations use the term "shoulder harness" and the aviation community readily identifies with this terminology, the term "shoulder harness" is retained in these amendments.

One commenter suggests that the safety benefits of the proposed rule would be significantly enhanced by requiring that manufacturers make available, within one year following the effective date of the amendment, shoulder harness kits suitable to retrofit previously produced airplanes of types in current production with "upper torso restraint systems" capable of satisfying the amended rule. The commenter further recommends that a subsequent date should then be established (e.g., two years thereafter) upon which installation of such modification kits by all owners would become mandatory. However, another commenter recommends that the installation of shoulder harnesses on existing airplanes remain on a voluntary basis. This issue is one of the subjects of a current FAA study to determine the economic viability of alternative 7. Shoulder harness retrofit kits for all seats are presently available from the manufacturers of nearly all small airplanes. Upon completion of the FAA study, a decision will be made on whether to proceed with further rulemaking.

One commenter requests that the proposal be revised to provide for the installation of aft-facing or club seating arrangements in airplanes with a seating capacity of six or more without installing shoulder harnesses for aft-facing seats since the seat back must be designed to withstand the inertia forces prescribed in § 23.561(d)(2) to comply with § 23.785(j) of the FAR. The FAA disagrees. A shoulder harness on an aft-facing seat will provide lateral restraint in many airplane accidents where motion is not parallel to the longitudinal axis of the airplane and also provides rebound protection.

One commenter states that although no specific mention of side-facing seats is made in the regulations, it would appear that installation of shoulder harnesses on these type seats might enhance injuries when occupants are subjected to the inertia forces of § 23.561(b)(2), and, therefore, there should be other means of protecting occupants of side-facing seats. This commenter suggests a requirement similar to § 23.785(e), which is applicable to berths. The FAA recognizes that providing an equivalent level of safety on side-facing or club seats may present the designer a more difficult task than forward- or aft-facing seats. Furthermore, the commenter did not provide any information or data on how a level of safety could be provided that would be equivalent to that which would accrue from the installation of shoulder harnesses on forward- and aft-facing seats.

The FAA does not have adequate data to define safety provisions for side-facing seats or club seating equivalent to that afforded in a forward- or aft-facing seat with a shoulder harness and does not consider the berth requirements to be adequate for seats. This rulemaking action defines the occupant restraint requirement for forward- and aft-facing seating and, if an applicant chooses to provide different seating arrangements, that applicant must provide adequate data to substantiate that those seating arrangements provide an equivalent level of safety. The FAA is clarifying the requirements being adopted in § 23.785(g) by stating that for seat orientations other than forward- and aft-facing, the seat and restraint means must be designed to provide a level of occupant protection equivalent to that provided for forward- and aft-facing seats with safety belts and shoulder harnesses installed in normal, utility, and acrobatic category airplanes. Also, in light of the proposal to adopt a commuter category airplane within Part 23 as set forth in Notice No. 83-17 (48 FR 52010, November 15, 1983), the FAA plans to retain the standards in effect on the date of issuance of Notice No. 83-17 respecting seat and shoulder harness requirements for commuter category airplanes.

One commenter expresses a hope that, concurrent with the installation of shoulder harness at every seat, the manufacturers will make a serious attempt to improve the function and comfort of occupant restraint belts. This commenter contends that many shoulder harness designs are not well matched to the range of human body forms and are extremely uncomfortable, even during short term use. In addition, this commenter states many current designs do not easily allow scanning of the airspace by pilots for potential traffic since the shoulder harness is unnecessarily restrictive and does not allow significant upper torso movement. Another commenter, in opposing the proposal, recommended that the FAA expend an effort in getting a proper aviation restraining device for the pilot and copilot's seats of existing airplanes. The FAA recognizes that improvements could be made over currently installed shoulder harnesses and is, therefore, requiring compliance with the requirements of § 23.785(h) for the flightcrew member seats of all newly manufactured airplanes by adoption of new §§ 23.2 and 91.33(b)(14).

One commenter states that the current 40 percent usage rate of shoulder harnesses needs to be improved. This commenter recommends that § 91.14(a)(3) be amended to require each occupant to use the available shoulder harness for takeoff and landing. The FAA agrees since the mere availability of shoulder harnesses does not achieve the purpose of having shoulder harnesses installed. Therefore, the FAA amends § 91.14(a)(3) as suggested by this commenter in order to achieve the level of safety intended by this rulemaking action. This commenter contends that a further improvement to safety could be made if each occupant were required, while en route, to keep the safety belt properly secured about his/her person while seated. The FAA agrees that this is a prudent practice but does not agree that the Federal Aviation Regulations should be amended to make this practice mandatory. Passengers can clearly visualize the need for properly secured restraint devices during takeoffs

and landing, but cannot visualize such a need in routine nonturbulent flight. Requiring restraint devices to be secured without a clear and identifiable need would tend to dilute the effectiveness of the requirement of § 91.14(a)(3), as adopted by this rulemaking.

The previous commenter states that, at the present time, because shoulder harnesses are optional, seats and safety belts in combination or by themselves must accommodate the loads prescribed in § 23.561. Additionally, the commenter contends that since the shoulder harness can transfer large loads directly to the fuselage, the shoulder harness could possibly carry a large portion of the prescribed 9 *g* load in a particular seat/safety belt/shoulder harness system. When the shoulder harness is made mandatory, this commenter states, designers will be in a position to reduce the strength of the seat/safety belt combination and meet the standard on the basis that the combined seat/safety belt/shoulder harness system accommodates the prescribed load. This commenter contends that the seat/safety belt combination, of itself, should continue to be required to withstand the prescribed load of 9 *g*, as should the shoulder harness, and the entire seat/safety belt/shoulder harness system. The FAA agrees that there should not be a lowering of the strength requirements for safety belts regardless of their combination with shoulder harnesses. This amendment does not revise the safety belt strength requirements of § 23.1413, but adds the should harness requirements to the airworthiness standards of § 23.785(g). In response to this comment, the FAA requires each safety belt and shoulder harness to comply with § 23.1413, which must meet the load prescribed in § 23.561(b)(2).

Two commenters oppose the proposal with regard to the installation of shoulder harnesses in newly manufactured airplanes to be operated in air commerce for compensation or hire, and in scheduled passenger operations pursuant to Part 135 of the FAR. One of these commenters contends that the FAA ignored that part of its petition for rulemaking which stipulated that the should harness installation should not be applicable to airplanes operated in air commerce for compensation or hire under Part 135 with a passenger seating configuration, excluding pilot seats, of nine or less. In response to this comment, the FAA did not ignore that part of the petition which stipulated that shoulder harnesses should not be applicable to airplanes operated pursuant to Part 135. The FAA evaluated the merits of this aspect and concluded that, irrespective of the type of operation, all newly manufactured normal, utility, and acrobatic category airplanes with a passenger seating capacity, excluding pilot seats, of nine or less should have shoulder harnesses installed at all seat positions. Arguments presented by the commenters do not persuade the FAA that the proposal should be changed. In support of Notice No. 85-11, the FAA's report entitled, "Crashworthiness Studies: Cabin, Seat, Restraint, and Injury Findings in Selected General Aviation Accidents", which is cited in the background paragraph of this amendment, concluded that shoulder harnesses enhance the crashworthiness of an airplane, and, thus, reduce the possibility of serious or fatal injuries to occupants of other seats, in addition to those seats occupied by the pilot and copilot or other front seat passenger. The second of these commenters states that the United States regional and commuter airlines currently operate 721 airplanes of nine or less passenger seats in scheduled Part 135 passenger service, of which 219 are single-engine airplanes. In addition, this commenter states that four basic types account for 64 percent of all airplanes of this size: the Cessna 206/207 series, the Cessna 402/404 series, the Piper PA-31 piston engine derivatives, and the Britten-Norman Islander series. The commenter states that these airplanes are equipped by the manufacturers with "airline interior options" and are completely different from the normal interior options purchased by personal and business use customers. It is contended that because the commuter airlines presently operate a substantial number of airplanes of the affected size (as well as larger airplanes) not equipped with shoulder harnesses, these operators do not want to introduce shoulder harnesses to their fleets. It is alleged that this reluctance is not due to a lack of awareness of safety, but rather stems from concern over the confusion and perceptions that will ensue among passengers boarding some commuter airplanes equipped with shoulder harnesses and some without shoulder harnesses. This commenter cites the safety records from the 1984 NTSB satatistics as 1.14 accidents per 100,000 flight hours for scheduled Part 135 operations, 4.24 accidents per 100,000 flight hours for on demand air taxi Part 135 operations, and 9.82 accidents per 100,000 flight hours for general aviation operations. The FAA recognizes, as this second commenter states, that the safety record of Part 135 scheduled passenger operations has been substantially better than the safety record for other types of operation with airplanes having nine or less passenger seats. In addition, this commenter contends that airplanes of the same type have a greater utilization rate in both number of flights and number of passengers carried in scheduled Part 135 operations than does the same type of airplane used in personal or business use; however, the high rate of use in Part 135 operations relative to the same airplane models in general aviation use exposes a substantially larger number of people to the unlikely event of an accident. Therefore, the installation of shoulder harnesses at all seats would provide an enhanced level of safety to a larger number of people for these airplanes when used in Part 135 operations. Relative to possible passenger confusion and perceptions among passengers relative to some airplanes having shoulder harnesses and some not having shoulder harnesses, the commenter did not state the nature of the anticipated confusion and perceptions and the FAA does not visualize any effect on the resulting level of safety—only that passengers might ask questions concerning the installation of the shoulder harnesses on new airplanes used in Part 135 operations. This same commenter also contends that the additional maintenance and passenger briefing effort would pose a very large burden on the Part 135 operators. This commenter presents neither information nor data to support this contention. The FAA does not agree that the installation of shoulder harnesses would impose any significant additional maintenance or briefing effort on Part 135 operators as maintenance and briefing efforts are presently required with respect to the safety belts in the affected airplanes.

One commenter contends that the implementation of the proposal is a gesture in futility disguised as safety and the only results will be more litigation directed at pilots and owners alleging neglect to properly brief passengers. This commenter states that there is no possible way of enforcing the requirements and will be hard pressed to get passengers to do that which they do not have to do on a commercial carrier. The FAA does not agree. This commenter presented no information to support the contention of more litigation or that passengers will not use shoulder harnesses for takeoffs and landings when available. In addition, § 13.1 of the FAR addresses the issue of reporting to the FAA any known violation of any regulation or order issued pursuant to the Federal Aviation Act of 1958, as

amended, and § 91.3 places the responsibility for operation of an airplane upon the pilot.

Another commenter states that the installation of shoulder harnesses in new airplanes is an unnecessary expense and the only thing that the proposal will do is raise the price of airplanes. The FAA does not agree that the installation of shoulder harnesses in new airplanes is an unnecessary expense because of the number of fatalities and serious injuries that will be prevented. With regard to raising the price of airplanes, those manufacturers which are GAMA members are presently installing on a voluntary basis shoulder harnesses at all seat positions and, therefore, no additional expense is being incurred that is not currently present in the price of new airplanes from these firms.

Sections 21.17 and 21.101 are amended to reference new § 23.2. These amendments are considered nonsubstantive, but are necessary to ensure that § 23.785, which is being made mandatorily retroactive, will be complied with and incorporated in the type certificate, amended type certificate, or supplemental type certificate, as appropriate. New § 23.2 could affect pending applications for type certificates at the time § 23.2 becomes effective. Also, compliance with § 23.2 for newly manufactured airplanes which were previously type certificated would require an amended type certificate or a supplemental type certificate. Accordingly, reference to new § 23.2 is needed in §§ 21.17 and 21.101.

The FAA is deleting the phrase "with a passenger seating configuration, excluding pilot seats, of nine or less" at the end of § 23.785(g), as stated in the notice. This phrase is redundant because of the general applicability of Part 23 with respect to the normal, utility, and acrobatic categories of airplanes, as set forth in § 23.1. New applications for a type certificate pursuant to Part 23 for normal, utility, and acrobatic category airplanes, is limited to airplanes with a passenger seating configuration, excluding pilot seats, of nine or less.

Economic Impact

The economic impact information provided below was prepared from the Final Regulatory Analysis.

It is estimated that the cost of a shoulder harness is about $150 to $250 per unit. The relatively high cost in relation to automobile seat belts is because of the low production volume and the requirement to carefully install the shoulder harness to make certain it is properly aligned. The life of a shoulder harness is estimated to be 10 years, depending on use, the timing of seat replacement, and the effects of sunlight on the belting material.

The benefit of a shoulder harness is the reduction in casualty loss attributable to the shoulder harness, that is, the number of lives and injuries saved by those using the shoulder harnesses who would have been killed or injured if they had not used the shoulder harness.

There were 480,000 passenger seats in the active general aviation fleet in 1981. There was an average of 670 passenger fatalities per year for the period 1979 through 1981. Therefore, the average fatality rate over the entire general aviation fleet was 126 per 100,000 seats.

The NTSB has conducted an analysis of 1982 accidents in which the utility of shoulder harnesses was evaluated. In these accidents, 40 percent of the occupants were wearing shoulder harnesses when available, and this was the estimate used for the calculation of benefits in the NPRM. Since this amendment revises the NPRM's proposal to now require each occupant to use the available shoulder harness for takeoff and landing, and because there has been an active education program by the general aviation community and the FAA to promote the use of shoulder harnesses, the FAA now estimates that shoulder harness use will increase to 60 to 80 percent. For the purpose of this analysis, 70 percent will be the estimated usage rate.

NTSB estimated that about 20 percent of the people killed could have survived if they had been wearing shoulder harnesses. Therefore, shoulder harnesses are likely to save about 17.6 people per 100,000 seats per year (70% of 20% X 126 fatalities per 100,000 seats). The FAA in 1984 valued a life at $670,000. Thus, over a 10 year period, the life of a shoulder harness, there would be a reduction in fatalities valued at $118 million for 100,000 seats. The cost of equipping these seats with shoulder harnesses is $20 million ($200 per seat x 100,000 seats). Since lives will be saved uniformly over the ten year period and the shoulder harness investment will be made in the first year, the benefit to cost ratio is about 3.5 taking into consideration the time value of money (the FAA uses 10%).

There was only one comment relating to the cost and benefits. One commenter indicates that Part 135 scheduled passenger operations is nine times safer overall than general aviation flying and, therefore, there was not as great a need for shoulder harnesses for this aviation segment. This comment was addressed in a previous section.

Additional detail relating to the economic impact can be found in the Regulatory Evaluation which has been placed in the docket.

Trade Impact

This rule would have little or no impact on trade for both U.S. firms doing business in foreign countries and foreign firms doing business in the U.S.

In the U.S., foreign manufacturers would have to meet U.S. requirements, and, thus, they would gain no competitive advantage. In foreign countries, U.S. manufacturers can be competitive by either installing or not installing shoulder harnesses depending on requirements. There were no comments relating to trade impact.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by government regulations. The RFA requires agencies to review rules which may have a significant economic impact on a substantial number of small entities.

The FAA's criteria for a small manufacturer is one with less than 75 employees, a substantial number is one which is not less than 11 and which is more than one-third of the small entities subject to the proposed rule, and a significant impact is one having an annual cost of more than $13,700 in 1984 dollars per manufacturer.

A review of the aircraft manufacturers indicates that there are less than eleven "small" manufacturers. In addition, members of the General Aviation Manufacturers Association (GAMA) are voluntarily installing shoulder harnesses and, therefore, this amendment will not impact these manufacturers whether large or small.

There were no comments relating to the initial regulatory flexibility determination.

Conclusion

The FAA has determined that this document involves regulations which are not considered to be major under the procedures and criteria prescribed by Executive Order 12291. However, this document is considered to be significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the regulatory evaluation prepared for this action is contained in the regulatory docket. A copy may be obtained from the person identified as the contact for

further information. Furthermore, the FAA certifies that this regulation will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act since few, if any, small entities are involved. In addition, this final rule will have little or no impact on trade opportunities for U.S. firms doing business overseas or for foreign firms doing business in the United States.

List of Subjects

14 CFR Part 21

Air transportation, Aircraft, Aviation safety, Safety.

14 CFR Part 23

Aircraft, Aviation safety, Safety, Air transportation, Tires.

14 CFR Part 91

Air carriers, Aviation safety, Safety, Aircraft, Aircraft pilots, Air traffic control, Liquor, Narcotics, Pilots, Airspace, Air transportation, Cargo, Smoking, Airports, Airworthiness directives and standards.

In consideration of the foregoing, the Federal Aviation Administration amends Parts 21, 23 and 91 of the Federal Aviation Regulations (14 CFR Parts 21, 23, and 91) as follows:

PART 21—CERTIFICATION PROCEDURES FOR PRODUCTS AND PARTS

1. The authority citation for Part 21 continues to read as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2), 42 U.S.C. 1857f-10, 4321 et. seq.; E.O. 11514; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983).

§ 21.17 [Amended]

2. Section 21.17 is amended by inserting "§ 23.2," immediately before "§ 25.2" in paragraph (a).

§ 21.101 [Amended]

3. Section 21.101 is amended by inserting "§ 23.2," immediately before "§ 25.2" in paragraph (a).

PART 23—AIRWORTHINESS STANDARDS: NORMAL, UTILITY, AND ACROBATIC CATEGORY AIRPLANES

1. The authority citation for Part 23 continues to read as follows:

Authority: 49. U.S.C. 1344, 1354(a), 1355, 1421, 1423, 1425, 1428, 1429, and 1430; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983).

2. A new § 23.2 is added to Part 23 to read as follows:

§ 23.2 Special retroactive requirements.

Notwithstanding §§ 21.17 and 21.101 of this chapter and irrespective of the type certification basis, each normal, utility, and acrobatic category airplane having a passenger seating configuration, excluding pilot seats, of nine or less, manufactured one year after December 12, 1985, or any such foreign manufactured airplane for entry into the U.S., must meet the requirements of § 23.785 (g) and (h). For the purpose of this paragraph, the date of manufacture is:

(a) The date the inspection acceptance records, or equivalent, reflect that the airplane is complete and meets the FAA Approved Type Design Data; or

(b) In the case of a foreign manufactured airplane, the date the foreign civil airworthiness authority certifies the airplane is complete and issues an original standard airworthiness certificate, or the equivalent in that country.

3. Section 23.785 is amended by adding the words "and shoulder harness" between the words "belt" and "fastened" within the parenthetical phrase of the first sentence of paragraph (j) and by revising paragraph (g) to read as follows:

§ 23.785 Seats, berths, safety belts, and harnesses.

* * * * *

(g) Each occupant must be protected from serious head injury when subjected to the inertia forces prescribed in § 23.561(b)(2) for normal, utility, and acrobatic category airplanes, by a safety belt and shoulder harness that is designed to prevent the head from contacting any injurious object for each forward- and aft-facing seat. For other seat orientations, the seat and restraint means must be designed to provide a level of occupant protection equivalent to that provided for forward- and aft-facing seats with safety belts and shoulder harnesses installed.

* * * * *

PART 91—GENERAL OPERATING AND FLIGHT RULES

1. The authority citation for Part 91 continues to read as follows:

Authority: 49 U.S.C. 1301(7), 1303, 1344, 1348, 1352 through 1355, 1401, 1421 through 1431, 1471, 1472, 1502, 1510, 1522, and 2121 through 2125; Articles 12, 29, 31, and 32(a) of the Convention on International Civil Aviation (61 Stat. 1180); 42 U.S.C. 4321 et seq.; E.O. 11514; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 21, 1983).

§ 91.14 [Amended]

2. Section 91.14 is amended by revising the title of § 91.14 to read as follows: "Use of safety belts and shoulder harnesses"; by adding the words "and shoulder harness, if installed", following the word "belt" in paragraph (a)(1); by adding the words "and shoulder harness, if installed" following the word "belt" in paragraph (a)(2); and by adding the words "and shoulder harness, if installed," following the word "belt" in paragraph (a)(3).

3. A new paragraph (b)(14) is added to § 91.33 to read as follows:

§ 91.33 Powered civil aircraft with standard category U.S. airworthiness certificates; instrument and equipment requirements.

* * * * *

(b) * * *

(14) For normal, utility, and acrobatic category airplanes with a seating configuration, excluding pilot seats, of nine or less, manufactured after December 12, 1986, a shoulder harness for—

(i) Each front seat that meets the requirements of § 23.785 (g) and (h) of this chapter in effect on December 12, 1985;

(ii) Each additional seat that meets the requirements of § 23.785(g) of this chapter in effect on December 12, 1985.

* * * * *

Issued in Washington, DC, on November 6, 1985.

Donald D. Engen,

Administrator.

[FR Doc. 85-26923 Filed 11-7-85; 1:34 pm]

BILLING CODE 4910-13-M

Federal Register

Wednesday
November 13, 1985

Part III

Environmental Protection Agency

40 CFR Parts 141 and 142
National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals; Final Rule and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[WH-FRL-2819-4(b)]

National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action under the Safe Drinking Water Act (42 USC 300f *et seq.*) promulgates Recommended Maximum Contaminant Levels (RMCLs) for the following eight volatile synthetic organic chemicals (VOCs) in drinking water: tricloroethylene, carbon tetrachloride, 1,1,1,-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1,-dichloroethylene, and p-dichlorobenzene. In the **Federal Register** notice of June 12, 1984, EPA proposed RMCLs for these eight compounds and tetrachloroethylene.

New data on the toxicology of tetrachloroethylene has recently become available and the public comment period on the RMCL for tetrachloroethylene is being reopened for 45 days in a separate Notice of Availability published in today's **Federal Register.** In this final rule notice, EPA examines the available data on tetrachloroethylene, including the new data together with the other eight VOCs. However, EPA will not promulgate an RMCL for tetrachloroethylene until after the close of the 45 day comment period.

RMCLs are *non-enforceable health goals* which are to be set at levels which would result in no known or anticipated adverse health effects with an adequate margin of safety. In this final rule, RMCLs for substances considered to be probable human carcinogens are set at zero and RMCLs for substances not treated as probable human carcinogens are based upon chronic toxicity or other data.

Maximum Contaminant Levels (MCLs) are *enforceable standards* and are to be set as close to the RMCLs as is feasible. MCLs are based upon treatment technologies, costs (affordability) and other feasibility factors, such as availability of analytical methods, treatment technology and costs for achieving various levels of removal. MCLs are being proposed for these eight VOCs in a separate **Federal Register** notice published today.

EFFECTIVE DATE: This rule is effective December 13, 1985.

ADDRESSES: Supporting documents cited in Section V will be available for inspection at the Drinking Water Supply Branches in EPA's Regional Offices.

I. JFK Federal Bldg., Boston, MA 02203. Phone: (617) 223–6486. Jerome Healy;
II. 26 Federal Plaza, Room 824, New York, NY 10278. Phone: (212) 264–1800. Walter Andrews;
III. 6th & Walnut Sts., Philadelphia, PA 19106. Phone: (215) 597–9873. Bernie Sarnoski;
IV. 345 Courtland Street, Atlanta, GA 30365. Phone: (404) 881–3781. Robert Jourdan;
V. 230 S. Dearborn St., Chicago, IL 60604. Phone: (312) 886–6176. Joseph Harrison;
VI. 1201 Elm St., Dallas, TX 75270. Phone: (214) 767–2620. James Graham;
VII. 726 Minnesota Ave., Kansas City, KS 66101. Phone: (913) 236–2815. Gerald R. Foree;
VIII. 1860 Lincoln St., Denver, CO 80295. Phone: (303) 293–1426. Marc Alston;
IX. 215 Fremont St., San Francisco, CA 94105. Phone: (415) 974–8076. Leslie Ragle;
X. 1200 Sixth Ave., Seattle, WA 98101. Phone: (206) 442–1225. Jerry Opatz.

Copies of the health effects and occurrence documents are available for a fee from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll free number is 800/336–4700; local: 703/487–4650. Other information on health effects and occurrence are included in the public docket.

The public docket for this final RMCL rule is part of the public docket for the National Primary Drinking Water Regulation proposed elsewhere in today's **Federal Register.** It is available for viewing at the address described in that notice. Comments are not solicited on this final rule.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH–550), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, telephone (202) 382–7575.

SUPPLEMENTARY INFORMATION:

I. Statutory Requirements and Regulatory Framework.
II. Background and Summary Comments.
III. Volatile Synthetic Organic Chemicals in Drinking Water.
A. Occurrence of VOCs in Drinking Water.
B. Human Health Considerations.
IV. Determination of RMCLs.
A. Selection of Contaminants for Regulation.
B. Basis for RMCLs.
1. Strength of Evidence of Carcinogenicity.
2. Three-Category Approach for Setting RMCLs.
3. RMCLs for VOCs Categorized by Three-Category Approach.
4. Final RMCLs.
5. Effective Dates.
V. Public Docket/References.
VI. Regulatory Analyses.

I. Statutory Requirements and Regulatory Framework

The Safe Drinking Water Act (42 U.S.C. 300f, *et seq.*) ("SDWA" or "the Act") requires the EPA to establish primary drinking water regulations which: (1) Apply to public water systems; (2) specify contaminants which in the judgment of the Administrator, may have any adverse effect on the health of persons; (3) specify for each contaminant either (a) MCLs or (b) treatment techniques. See section 1401(1), 42 U.S.C. 300f. A treatment technique requirement would only be set if "it is not economically or technologically feasible" to ascertain the level of a contaminant in drinking water.

The SDWA includes provisions for interim and revised regulations. See section 1412, 42 U.S.C. 300g–1. Interim regulations were to be established within 180 days of enactment of the SDWA. Revised regulations are to be developed in two steps: the Agency is to establish RMCLs and then establish MCLs as close to the RMCLs as feasible. MCLs are to be proposed at the time of promulgation of the RMCLs.

RMCLs are non-enforceable health goals. RMCLs are to be set at a level at which, in the Administrator's judgment, "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". Section 1412(b)(1)(B). The House Report on the SDWA provides Congressional guidance on developing RMCLs:

> . . . the recommended maximum level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at zero level.

House Report No. 93–1185, July 10, 1974, at 20. In addition, a list of contaminants is to be included in the regulations for "any contaminant the level of which cannot be accurately enough measured in drinking water to establish a Recommended Maximum Contaminant Level and which may have any adverse

effect upon the health of persons". Section 1412(b)(1)(B).

MCLs are the enforceable standards. MCLs must be set as close to RMCLs as is "feasible". Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)." Section 1412(b)(3).

RMCLs of themselves have no legal impact on public water systems or the public. By promulgating RMCLs, no system is forced to remove contaminants to this level or to take other action regarding contaminants. RMCLs only serve as goals for the Agency in the course of setting MCLs and are therefore initial steps in the MCL rulemaking. In some cases, the MCLs will be set very close to the RMCLs; in other cases control processes or economic considerations may dictate an MCL that is not as close. In any case, it is the MCLs that must be met by public water systems. Non-compliance with an RMCL cannot be the basis of an enforcement action under Section 1414 of the Safe Drinking Water Act. Under Section 1413 of the Act, to receive and maintain primary enforcement responsibility, States must adopt MCLs that are no less stringent than EPA requirements. States are not required to adopt RMCLs to receive or maintain primary enforcement responsibility.

II. Background and Summary of Comments

EPA has received significant comment and advice on these final RMCLs. Over the last 10 years, EPA has consulted the National Academy of Sciences, industry groups, chemical trade associations, the National Drinking Water Advisory Council, other Federal Agencies, and the public. EPA published an Advance Notice of Proposed Rulemaking and a Proposal and received a substantial volume of comments. All of these views and information have been carefully weighed in developing this final rule.

On June 12, 1984, EPA proposed RMCLs for nine VOCs in drinking water: trichloroethylene, tetrachloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and p-dichlorobenzene. The RMCLs for those chemicals considered to be carcinogens were proposed at zero, and the RMCLs for the non-carcinogens were proposed based upon chronic toxicity data. This proposal was preceded by an Advanced Notice of Proposed Rulemaking (47 FR 9350) which discussed regulatory and non-regulatory approaches to limiting exposure to VOCs in drinking water.

EPA received 95 public comments on the June 12, 1984, RMCL proposal. The three major issues discussed in the public comments were:

1. Should RMCLs for carcinogens be set at zero?
2. How should the strength of evidence of carcinogenicity be factored into the RMCL determinations?
3. What is the appropriate RMCL for chemicals with limited evidence of carcinogenicity (i.e., trichloroethylene, tetrachloroethylene and 1,1-dichloroethylene)?

The following is a discussion of the major public comments received on these key issues:

Seventy-three commenters addressed the issue of whether RMCLs for carcinogens should be set at zero, as was proposed in the RMCL proposal. Twenty-six of the commenters stated that RMCLs for carcinogens should be set at zero, while forty-seven commenters did not agree.

The primary basis for the commenters favoring a zero level was the legislative history of the SDWA which stated that the RMCLs s for contaminants for which there is no safe threshold should be set at zero. In addition, many of these commenters expressed the opinion that carcinogens should not be present in drinking water at any level and RMCLs at zero were an appropriate expression of this philosophy.

The major reasons why the commenters did not favor setting the RMCLs at zero were that zero is not measureable or attainable and it is scientifically undefinable. These commenters generally felt that RMCLs should be achievable levels which would provide actual guidance on levels attainable in public water systems.

EPA believes that zero is the appropriate RMCL goal for substances assumed to be non-threshold toxicants in the absence of countervailing data. This approach is consistent with the legislative history of the SDWA. Substances with sufficient evidence to be regulated as probable carcinogens have been assigned RMCLs of zero.

EPA concluded that the two other suggested approaches for setting RMCLs for carcinogens, limit of detection or target risk, were inappropriate as regulatory methods for establishing a health goal. Detection limits are not a function of health risk. EPA rejected target risk (e.g., 10^{-6}) for probable human carcinogens because it believed that an RMCL of zero was more consistent with the SDWA mandate and legislative history.

Seven comments were received in which strategies for factoring the strength of evidence of carcinogenicity in the RMCL determinations were presented. The majority of these commenters suggested that RMCLs be set at varying risk levels depending on the strength of evidence; for example, RMCLs would be set at the 10^{-6}) risk level for known carcinogens and at a 10^{-5}) risk level for compounds with limited evidence of carcinogenicity. One commenter presented an alternate approach in which VOC scores based upon the quantitative and qualitative evidence of carcinogenicity were assigned to each chemical. Arbitrary concentration levels were then to be assigned to each letter score and an Adjusted Acceptable Daily Intake (AADI) was calculated for each chemical. The AADI was compared to the arbitrary concentration level and the lower value was used as the RMCL.

An additional eighteen coments were received which addressed how strong the strength of evidence should be to justify regulating a substance. Thirteen commenters suggested that strength of evidence should be used to determine which chemicals should be regulated and five of these commenters stated that EPA should establish minimum criteria for regulating a substance as a carcinogen, based upon the International Agency for Research on Cancer (IARC) criteria.

EPA agrees with the comments suggesting that strength of evidence of carcinogenicity be considered in setting the RMCLs. EPA also agrees with those commenters who suggested that those substances with sufficient evidence to be considered probable human carcinogens should be regulated in a more stringent manner than those contaminants with less carcinogenic evidence. EPA is using a three-category approach for setting RMCLs in which chemicals are classified based upon their strength of evidence of carcinogenicity. This approach is based upon the EPA Proposed Guidelines for Carcinogen Risk Assessment (49 FR 46294).

The EPA Guidelines were proposed subsequent to the June 12, 1984 proposal and contain a categorization scheme based upon the IARC criteria. This scheme divided chemicals into five groups, ranging from strong evidence of carcinogenicity to humans to no evidence of carcinogenicity, based upon a qualitative evaluation of the available data. EPA is using this categorization scheme to divide the chemicals based upon their strength of evidence. The top two rankings, human carcinogen or animal carcinogen (A, B), are being treated as probable human carcinogens with RMCLs of zero. RMCLs for the

third rank, limited evidence of animal carcinogenicity (C), are computed non-zero values determined by the quality of data, and RMCLs for the lower two ranks, inadequate or no evidence of carcinogenicity (D and E), are computed by classical Acceptable Daily Intake (ADI) procedures.

Several comments were received which addressed the RMCLs for specific chemicals. The majority of comments regarding trichloroethylene, tetrachloroethylene and 1,1-dichloroethylene stated that these chemicals should not be regulated as confirmed carcinogens and the RMCLs should be set based upon chronic toxicity data.

EPA has evaluated these chemicals using the EPA proposed guidelines for carcinogen risk assessment. EPA agrees that there is insufficient evidence at this time to consider 1,1-dichloroethylene as a probable human carcinogen and this compound has been ranked in EPA's Guideline Level C (limited evidence of animal carcinogenicity). In the three-category approach, the RMCLs for Category II chemicals (EPA's Guideline C) are set based either upon chronic toxicity data with an extra uncertainty factor or by use of risk extrapolation methods. The decision whether to use chronic toxicity data with an uncertainty factor of risk extrapolation methods is made on a case-by-case basis depending upon the adequacy of the data.

EPA has evaluated the data for trichloro-ethylene and tetrachloro-ethylene and has concluded that there is sufficient evidence to consider the compounds as probable human carcinogens. Thus, the RMCL for trichloroethylene will remain at zero, based upon its classification in EPA's Proposed Guidelines. The final RMCL for tetrachloroethylene will be promulgated after the close of 45-day comment period.

Appendix A presents more a detailed summary and discussion of the principal comments with EPA's responses to the comments. Additional comment and responses are contained in the background document, "Summary of Comments and EPA Responses on Federal Register Notices on Volatile Organic Chemicals in Drinking Water".

III. Volatile Synthetic Organic Chemicals in Drinking Water

The June 12, 1984, Federal Register notice summarized the available information on the occurrence of VOCs in drinking water, population exposure estimates and toxicology data. Detailed information was presented in the Health Criteria and Occurrence Documents. The following information is intended to briefly summarize available occurrence data and health considerations.

A. Occurrence of VOCs in Drinking Water

The EPA has conducted six national surveys since 1975: the National Organics Reconnaissance Survey (NORS), the National Organics Monitoring Survey (NOMS), the National Screening Program (NSP), the Community Water Supply Survey (CWSS), the Ground Water Supply Survey (GWSS) and the Rural Water Survey (RWS).

The NORS and NOMS were initiated in 1975 and primarily examined the presence of trihalomethanes in U.S. drinking water supplies. The NSP, which examined 168 water supplies between 1977 and 1981, and the CWSS, which was conducted in 1978, have demonstrated the presence in surface waters of organic contaminants in drinking water, generally at levels less than 10 μg/l.

The GWSS was conducted in 1982 and consisted of a survey of approximately 100 drinking water supplies which used ground water as a source. Five hundred supplies were selected at random and 500 were selected by States as having high potential for contamination by organic chemicals. The results showed that in the random portion of the survey, approximately 21 percent of the systems had one or more volatile organic chemicals at detectable levels (primarily in the low μg/l range). Approximately 16 percent of the smaller systems (<10,000 people) in the random sample contained some concentrations of the VOCs at levels above the quantitation limit and less than 1 μg/l, while approximately 28 percent of the large supplies (>10,000 people) contained these levels of VOCs. In the non-random portion of the survey, higher frequencies of occurrence were found at all levels. Table 1 presents a summary of occurrence data.

TABLE 1.—OCCURRENCE OF VOCs IN DRINKING WATER

Compound	Summary of GWSS occurrence data (random sample; n=466)		Summary of State occurrence data[1]	
	Positives		Number of samples	Number of positives
	Number	Percent		
Tetrachloroethylene	34	7.3	3,636	626
Trichloroethylene	30	6.4	4,228	624
1,1,1-Trichloroethane	27	5.8	3,330	715
1,1-Dichloroethane	18	3.9	2,626	177
1,2-Dichloroethylenes	16	3.4	1,249	197
Carbon tetrachloride	15	3.2	2,646	368
1,1-Dichloroethylene	9	1.9		
p-Dichlorobenzene	5	1.1		
Vinyl chloride	1	0.2	1,793	126

[1] The State data represent a collection of available data from various State agencies, are normally in response to contamination incidents, and are not considered to be statistically representative of national occurrence.

The nine VOCs have been detected in public drinking water supplies at various concentration levels. The following is a summary of the occurrence information based upon combined data from the national surveys.

Compound	Concentration range (μg/l) in public drinking water systems
Benzene	0.2-22
Carbon tetrachloride	0.5-30
p-Dichlorobenzene	0.1-30
1,2-Dichloroethane	0.2-21
1,1-Dichloroethylene	0.2-6.3
Tetrachloroethylene	0.1-69
1,1,1-Trichloroethane	0.8-142
Trichloroethylene	0.2-160
Vinyl chloride	0.2-66

Available data on the use, release, and occurrence of halogenated volatile organics strongly suggests the widespread *in situ* transformation of a number of 2 carbon halogenated compounds. The compounds involved include trichloroethylene, tetrachloroethylene, cis- and trans-1,2-dichloroethylene, vinyl chloride, 1,1,1-trichloroethane and 1,1-dichloroethylene. Transformations of some of the above chemicals have been demonstrated in laboratory and field studies.

A limited number of laboratory studies have shown that trichloroethylene and tetrachloroethylene can be sequentially dechlorinated to form cis- and trans-1,2-dichloroethylene, vinyl chloride and finally Cl^- and CO_2. There is some suggestion that 1,1-dichloroethylene, may also be produced in the same

degradation process. Other studies have shown that 1,1,1-trichloroethane can be dechlorinated to form 1,1-dichloroethane and chloroethane. The evidence for degradation falls into two categories: first, the low commercial production and release of a number of compounds with widespread occurrence, and second, the high degree of co-occurrence of compounds with their suspected degradation products.

In summary, the available data on occurrence supports the hypotheses that the major source of ground water contamination for vinyl chloride, 1,2-dichloroethylene, and 1,1-dichloroethylene is the decomposition of trichloroethylene and tetrachloroethylene and that the major source of 1,1-dichloroethane is the degradation of 1,1,1-trichloroethane. The data also suggest that chloroethane may also be a contaminant of ground water. Since trichloroethylene, tetrachloroethylene, and 1,1,1-trichloroethane are widely released in the environment, their degradation products are also expected to have a wide occurrence. The occurrence documents referenced in Section V summarize available data to support these hypotheses.

B. Human Health Considerations

Exposure at very high levels to the VOCs for which RMCLs are proposed has been shown to result in a variety of acute and chronic toxic effects in animals. These levels are usually much higher than those found in public drinking water supplies. Damage to the liver and kidneys is a common effect demonstrated in animals from high exposure to several VOCs, as well as central nervous system effects and cardiovascular changes.

Carcinogenic effects have also been demonstrated from exposure to certain of these VOCs. Two of these compounds are demonstrated human carcinogens, while others have exhibited carcinogenic effects in animal studies. The evidence of carcinogenicity for these nine compounds ranges from sufficient evidence in humans to very limited or no evidence in animals.

Excess cancer risk rates have been calculated for the VOCs using a variety of models including the one-hit model, the Weibull model and the multi-stage model. Table 2 presents various risk estimates (95% confidence limit) using the multistage model, as calculated by EPA's Carcinogen Assessment Group (CAG) and the National Academy of Sciences (NAS).

TABLE 2.—CANCER RISK ESTIMATES FOR VOCs

Compound	Concentration in drinking water (µg/1) corresponding to a 10^{-4} risk	
	NAS	CAG[1]
Trichloroethylene	45	26
Tetrachloroethylene	35	6.7
Carbon tetrachloride	45	2.7
1,2-Dichloroethane	7.0	3.8
Vinyl chloride	10	0.15
1,1-Dichloroethylene	NC	0.61
Benzene	NC	13

[1] These calculations represent the most recent calculations by CAG.
NC=Not calculated.

In the June 12, 1984, RMCL proposal, chemicals were divided into two groups (carcinogens and non-carcinogens) and the RMCLs were proposed on a separate basis for each group. Based upon comments received, in this final action, chemicals are divided into three groups (probable human carcinogens, equivocal evidence of carcinogenicity and non-carcinogens) and the RMCLs set on different basis for each group. Section IV (Determination of RMCLs) discusses the methodology and basis for determining the RMCLs in this notice.

Acceptable Daily Intakes (ADIs) have been calculated for these nine compounds, following the procedure outlined in the RMCL proposal (49 FR 24330). In the proposal and this final rule, these ADIs are converted to solely represent drinking water intake (i.e., mg/l) and termed Adjusted ADIs (AADIs).

IV. Determination of RMCLs

The SDWA authorizes EPA to establish RMCLs for "each contaminant which, in [the Administrator's] judgment . . . may have any adverse effect on the health of persons" Section 1412(b)(1)(B). RMCLs are to be set at a level to prevent known or anticipated adverse effects and which allows an adequate margin of safety. Presented below are discussions of (1) the factors used to select the VOCs for regulation and (2) the methodology and basis for determining what levels are appropriate for the RMCLs.

A. Selection of Contaminants for Regulation

The June 12, 1984, Federal Register notice discussed the major factors considered in determining which VOCs should be regulated. This section provides a further discussion of the factors used to select the specific VOCs for which RMCLs are being promulgated at this time.

The three primary criteria for selection of contaminants for MCL regulations under the SDWA are: (1) The analytical ability to detect a contaminant in drinking water, (2) the potential health risk, and (3) the occurrence or potential for occurrence in drinking water.

General selection criteria have been developed which essentially expand the three primary factors listed above. Use of a specific formula to apply the selection criteria is appropriate because of the many unquantifiable variables; however, a decision-making "logic train" has been developed which incorporates the selection criteria and provides a framework from which to make appropriate determinations. Given the variability associated with exposure and human health aspects of drinking water contaminants and the directives of the SDWA, the decision criteria must remain flexible such that a case-by-case decision can be made for each contaminant. Nevertheless, the decision criteria do set forth an operative framework. For each contaminant, the essential factors in the analysis are as follows:

- Is it possible to detect the contaminant in drinking water at any level by analytical methods? If not, a drinking water regulation is probably inappropriate.
- Are there sufficient health effects data upon which to make a judgment on an RMCL? Are there potential adverse health effects of exposure to the contaminant via ingestion?
- Does the contaminant occur in drinking water?

—Has the contaminant been detected in significant frequencies and in a widespread manner in drinking water?

—If data are limited on the frequency and nature of contamination, is there a significant potential of drinking water contamination?

From the list of VOCs in the March 4, 1982, ANPRM (47 FR 9350), nine contaminants were selected for inclusion in the June 12, 1984, Federal Register notice as proposed RMCLs. Available data on each of the chemicals on analytical methods, health effects, occurrence, and potential occurrence were evaluated using the selection criteria and framework outlined above. The following chemicals were proposed for regulation: trichloroethylene, tetrachloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene and p-dichlorobenzene.

Three EPA approved analytical methods are available for measurement

of all nine VOCs at approximately $150 per sample.

Trichloroethylene, tetrachloroethylene and 1,1,1-trichloroethane were proposed for regulation based upon: (1) Occurrence data which showed these compounds to be present at significant frequencies in drinking water supplies; and (2) evidence of toxic effects. The random portion of the Ground Water Supply Survey (GWSS) reported that trichloroethylene was detected in 6.4 percent of the supplies, tetrachloroethylene in 7.3 percent of the supplies and 1,1,1-trichloroethane in 5.8 percent of the supplies sampled.

Carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethylene, vinyl chloride and benzene were also detected in the GWSS but at lower frequencies. RMCLs were proposed for these compounds based upon their occurrence and toxicology. Vinyl chloride and benzene are known human carcinogens, while carbon tetrachloride and 1,2-dichloroethane have strong evidence of carcinogenicity in animals.

An RMCL was proposed for p-dichlorobenzene based upon its detection in a limited number of drinking water systems, its potential for further drinking water contamination and toxic effects.

RMCLs were not proposed for cis- and trans-1,2-dichloroethylene, chlorobenzene, trichlorobenzene and methylene chloride in the June 12 proposal. RMCLs were not proposed for cis- and trans-1,2-dichloroethylene and chlorobenzene because toxicology evaluations were not complete at the time of the proposal; however, these evaluations have since been completed and RMCLs are included in the Phase II RMCL proposal. Occurrence data were not available for trichlorobenzene due to analytical difficulties in obtaining samples in the Ground Water Supply Survey. The toxicology data available for methylene chloride at the time of proposal did not permit a determination of health risks. However, new toxicology data has recently become available and is presently being evaluated. In addition, the available occurrence data were not considered reliable due to problems with laboratory contamination and quality assurance. Both of these chemicals will be considered in later phases of the Revised Regulations.

B. Basis for RMCLs

The June 12, 1984, **Federal Register** notice discussed three main options for setting RMCLs for carcinogens and requested comment on these options. These options were: (1) Set RMCLs at zero, (2) set RMCLs at the analytical detection limit, or (3) set RMCLs at a non-zero level based upon a calculated negligible contribution to lifetime risk. In addition, comment was requested on the strength of evidence needed to justify regulating a compound as a carcinogen, and on factoring the degree of evidence of potential carcinogenicity into the RMCL determinations. Several options were suggested.

The consideration of RMCLs set at zero for potential human carcinogens centered on the legislative history of the SDWA which stated that,

> . . . the recommended maximum (contaminant) level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at zero level.

In the proposal, RMCLs were proposed at zero for those substances which in EPA's view had at least "limited" evidence of carcinogenicity: tetrachloroethylene, trichloroethylene, carbon tetrachloride, 1,2-dichloroethane, vinyl chloride, benzene and 1,1-dichloroethylene. The basis for proposing RMCLs at zero was that the existence of a threshold for the action of potential carcinogens cannot be demonstrated by current science; it was conservatively believed that no threshold exists, absent evidence to the contrary. EPA also concluded that there was insufficient basis to distinguish between mechanisms of carcinogenicity (e.g., genotoxicity or others). Following the guidance provided in the legislative history, the RMCLs were proposed at zero. In addition, the Agency stated that setting RMCLs at zero for carcinogens would present a general philosophy that as a goal, carcinogens should not be present in drinking water.

1. Strength of Evidence of Carcinogenicity

The questions raised in the RMCL proposal concerning strength of evidence centered on the evidentiary threshold required to conclude that a substance should be considered to be a "carcinogen" for the purpose of this regulation. Chemicals have varying degrees and qualities of evidence concerning their potential carcinogenicity. EPA requested comment on how this evidence could be used in determining the RMCLs and also on the classification of chemicals according to their strength of evidence of carcinogenicity.

The commenters generally supported the use of strength of evidence in determining the RMCLs, but disagreed over the way in which the strength of evidence should be applied. A number of commenters stated that EPA should factor strength of evidence in the RMCLs based upon the IARC criteria. Several commenters felt that a compound should only be regulated as a carcinogen if there is evidence of human carcinogenicity or strong evidence of animal carcinogenicity, while others felt that a substance with "limited" evidence of carcinogenicity should be regulated as a carcinogen. A number of commenters proposed schemes for factoring the degree of evidence of carcinogenicity in the RMCL determinations.

- Two commenters proposed an approach in which RMCLs were set at zero for known human carcinogens, at a 10^{-6} lifetime cancer risk level for compounds with strong evidence of carcinogenicity in animals and at a 10^{-5} lifetime risk level for compounds with limited evidence in animals.
- Another approach consisted of setting RMCLs for known human and animal carcinogens at the 10^{-5} to 10^{-6} lifetime risk levels and setting RMCLs for those with limited evidence of animal carcinogenicity at the 10^{-4} to 10^{-5} lifetime risk levels.

As noted above, after the RMCL proposal, EPA proposed an approach for classifying chemicals based upon the strength of evidence of carcinogenicity (Proposed Guidelines for Carcinogen Risk Assessment 49 FR 46294, November 1984). EPA proposed a categorization scheme based upon the International Agency for Research on Cancer (IARC) criteria. The categorization consists of a five category approach, as shown below. In contrast, the IARC classification consists of three categories with the primary difference being that IARC does not distinguish between those with chemicals with inadequate animal evidence of carcinogenicity and those chemicals with no evidence for carcinogenicity, while the EPA scheme makes that distinction.

EPA Proposed Categorization for Carcinogens

Group A—Human carcinogen (sufficient evidence from epidemiological studies).

Group B—Probable human carcinogen.

Group B1—At least limited evidence of carcinogenicity to humans.

Group B2—Usually a combination of sufficient evidence in animals and inadequate data in humans.

Group C—Possible human carcinogen (limited evidence of carcinogenicity in animals in the absence of human data).

Group D—Not classified (inadequate animal evidence of carcinogenicity).
Group E—No evidence of carcinogenicity for humans (no evidence for carcinogenicity in at least two adequate animal tests in different species or in both epidemiological and animal studies).

IARC Criteria

Group 1—Chemical is carcinogenic to humans (sufficient evidence from epidemiological studies).
Group 2—Chemical is probably carcinogenic to humans.
Group 2A—At least limited evidence of carcinogenicity to humans.
Group 2B—Usually a combination of sufficient evidence in animals and inadequate data in humans.
Group 3—Chemical cannot be classified as to its carcinogenicity to humans.

Both of these classification schemes are based upon a qualitative review of all available evidence. Information considered in each assessment include short-term tests, long-term animal studies, human studies, pharmacokinetic studies, comparative metabolism studies, structure—activity relationships and other relevant toxicological studies.

Other groups have also supported the concept of assessing carcinogens by degree of evidence. The National Academy of Sciences (NAS) in *Drinking Water and Health*, 1977, Vol. I, classified chemicals with carcinogenic effects into four groups: human carcinogens, suspected human carcinogens, animal carcinogens and suspected animal carcinogens.

The U.S. Office of Science and Technology Policy's recent review of the science and associated principles of chemical carcinogenic risk (50 FR 10372) generated a series of principles to be used to establish specific guidelines for assessing carcinogenic risk. The review discussed the type of tests (short- and long-term) used to assess potential carcinogens and the interpretation of data in light of the strength of evidence. A classification system for carcinogens was not provided in the report.

Table 3 classifies the VOCs based upon an assessment under the EPA and IARC criteria. These classifications will be revised if new data on the VOCs dictate reclassification. In addition, EPA will reconsider these classifications if the final EPA Guidelines for Carcinogen Risk Assessment vary significantly from the proposed EPA guidelines.

TABLE 3.—STRENGTH OF EVIDENCE OF VOCs

Compound	Evidence of Carcinogenicity	EPA guidelines	IARC classification
Trichloroethylene	Carcinogenic in several strains of mice by the inhalation and oral route. Weakly mutagenic.	B2*	3
Tetrachloroethylene	Carcinogenic in mice by gavage and mice and rats by the inhalation route. Inconclusive mutagenicity data.	B2	3
Carbon Tetrachloride	Carcinogenic in 3 species by the oral route.	B2	2B
1,2-Dichloroethane	Carcinogenic in 2 species by the oral route.	B2	2B
Vinyl Chloride	Carcinogenic in animals by the inhalation and oral route and carcinogenic in humans by inhalation.	A	1
Benzene	Carcinogenic in animals and humans by inhalation and in animals by gavage.	A	1
1,1-Dichloroethylene	Two positive studies in mice and rats by the inhalation route and many negative studies by the inhalation and oral routes. Positive mutagenicity data.	C	3
p-Dichlorobenzene	Negative results (draft) in several animal species.	D	3
1,1,1-Trichloroethane	Preliminary animal evidence being audited. Inadequate human evidence.	D	3

*Classified by the EPA Risk Assessment Forum: an Agency-wide advisory group to the EPA Administrator.

2. Three-Category Approach for Setting RMCLs

The June 12, 1984, RMCL proposal consisted of a two-category approach to setting RMCLs; chemicals were classified as carcinogens or non-carcinogens. All chemicals with evidence of carcinogenicity ranging from limited to sufficient were classified as "carcinogens" and their RMCLs were proposed at zero. As noted, a number of commenters pointed out that this approach did not adequately take into account the varying degrees of evidence of the chemicals classified as carcinogens. In response to comment and consistent with the EPA guidelines, EPA is using this scheme in its final RMCL rule. This approach to setting RMCLs considers all of the available scientific data.

Table 4 describes this approach for setting RMCLs based upon the EPA classification system. The corresponding IARC classifications are included in the table for comparative purposes.

Table 4

Three-Category Approach for Setting RMCLs

Category I—Known or probable human carcinogens: Strong evidence of carcinogenicity.
- EPA Group A or Group B
- IARC Group 1, 2A or 2B

Category II—Equivocal evidence of carcinogenicity.
- EPA Group C
- IARC Group 3

Category III—Non-carcinogens: Inadequate or no evidence of carcinogenicity in animals.
- EPA Group D or E
- IARC Group 3

Category I includes those chemicals which, in the judgment of EPA, have sufficient human or animal evidence of carcinogenicity to warrant their regulation as known or probable human carcinogens. The approach to setting RMCLs for these compounds is not changed from the RMCL proposal; RMCLs are set at zero. These compounds are potential human carcinogens and they have not been demonstrated to exhibit a threshold; thus it is believed for the purpose of regulation that any exposure could contribute some finite level of risk.

Category II includes those chemicals for which some limited but insufficient evidence of carcinogenicity exists from animal data. These will not be regulated in the same manner as known or probable human carcinogens. However, RMCLs will reflect the fact that some experimental evidence of carcinogenicity in animals has been reported.

EPA has considered two main options for setting the RMCLs for these types of chemicals. The first option consists of setting the RMCL based upon non-carcinogenic endpoints (the AADI) if adequate data exist. To account for the equivocal evidence of carcinogenicity, an additional uncertainty factor would be applied (e.g., AADI divided by a factor of 10 or some other value). A factor of 10 would be applied in most cases because uncertainty factors have historically been applied in order of magnitude increments, with each additional ten-fold factor accounting for an added measure of uncertainty. However, uncertainty factors other than 10 would be applied if the data indicated the need for a greater or lesser extra safety margin. An example of when a greater uncertainty factor would be applied is if the AADI was based upon a weak study with a lack of supporting data. A lesser uncertainty factor would be applied in instances

when a great deal of strong epidemiology data exists. The second option consists of setting the RMCL based upon a lifetime risk calculation in the range of 10^{-5} to 10^{-6} using a conservative method (i.e., a method that may overestimate the risk) such as the linear multi-stage model. This is intended to be protective for compounds that are not being considered carcinogens, but for which questions have been raised concerning potential effects. EPA will use the first option if valid non-carcinogenic data are available upon which to base an ADI. If valid non-carcinogenic data are not available and risk levels can be calculated from adequate data, then risk calculations will be used.

EPA believes that both of these approaches reflect the primary consideration concerning Category II chemicals: RMCLs should be less conservative than those for Category I chemicals and more conservative than those for Category III chemicals. This is reflective of the quantity and quality of the toxicology data that are available. For the contaminant regulated under this category, in this rulemaking, it is clear that there is ample evidence to regulate the chemical based on evidence of adverse health effects unrelated to carcinogenicity. Thus, EPA is merely regulating this contaminant more conservatively as a result of the equivocal evidence of carcinogenicity. In regulating this contaminant, EPA is not regulating it based solely on equivocal evidence of carcinogenicity.

Category III includes those substances with inadequate or no evidence of carcinogenicity. RMCLs will be calculated based upon chronic toxicity data using ADIs as proposed. The ADI approach is well accepted in the scientific community as a method for determining acceptable exposure levels for threshold toxicants and was supported by the majority of commenters on the RMCL proposal. As proposed, an exposure factor of 20 percent contribution from drinking water is used conservatively to determine the RMCLs. This contribution factor is included because there is often an inadequate data base to precisely calculate multi-media exposure contributions for a cross section of the population. Drinking water is frequently a minor contribution to total exposure. In "Drinking Water and Health" (1977), the NAS provided projections of one percent and 20 percent as illustrations of drinking water contributions. The National Interim Primary Drinking Water Regulations also assumed that drinking water contributed 20 percent of the total daily intake for six organic chemicals. This approach was most consistently supported by commenters to both the ANPRM and RMCL proposal among those suggested.

3. RMCLs for VOCs Categorized by Three-Category Approach

Table 5 presents a distribution of the nine VOCs among the three categories.

Table 5

VOCs Using Three Category Regulatory Approach

Category I—Known or Probable Human Carcinogens: Strong evidence of carcinogenicity.
- Benzene
- Vinyl chloride
- Carbon tetrachloride
- 1,2-Dichloroethane
- Trichloroethylene
- Tetrachloroethylene

Category II—Equivocal Evidence of Carcinogenicity.
- 1,1-Dichloroethylene

Category III—Non-Carcinogens: Inadequate or no evidence of carcinogenicity in animals.
- 1,1,1-Trichloroethane
- p-Dichlorobenzene

The following are short discussions of the rationale for the placement of each VOC in its respective category. A more extensive discussion can be found in the Health Effects Criteria Documents referenced in Section V.

Benzene. Benzene has been placed in Regulatory Category I, based upon its documented carcinogenic effects in humans. Reported effects in humans include myelocytic anemia, thrombocytopenia and leukemia, particularly acute myelogenous and monocytic leukemia. Exposure to benzene has also been shown to result in carcinogenic effects in animals; several studies have shown an increase in tumors and leukemias in benzene-exposed animals. The IARC has categorized benzene in Group 1, sufficient evidence of carcinogenicity in humans. The NAS has classified benzene as a suspect human carcinogen. EPA has classified benzene in EPA's Group A, sufficient evidence from epidemiological studies.

Vinyl chloride. Vinyl chloride has been shown to have carcinogenic effects in humans and animals. In humans, exposure to vinyl chloride is associated with angiosarcoma of the liver. In animals, serveral tumor types including mammary carcinomas, liver angiosarcomas and pulmonary angiosarcomas have been reported following exposure to vinyl chloride through ingestion or inhalation. Vinyl chloride has exhibited a significant degree of DNA binding in short-term studies. The IARC has classified vinyl chloride in Group 1, sufficient evidence of carcinogenicity to humans. The NAS has classified vinyl chloride as a human carcinogen. EPA has classified vinyl chloride in EPA's Group A; sufficient evidence from epidemiological studies. Vinyl chloride has been placed in Regulatory Category I, based upon its carcinogenic effects, as described above, in humans and animals.

Carbon tetrachloride. Carbon tetrachloride has been shown to be carcinogenic in rats, mice and hamsters through oral exposure. Hepatocellular carcinomas have been observed in several animal studies as a result of carbon tetrachloride exposure. Carbon tetrachloride has been identified as an animal carcinogen by the National Cancer Institute (NCI) and has been used as a positive control in several bioassays. The IARC has concluded that sufficient evidence of carcinogenicity in animals exists for carbon tetrachloride and has classified the compound in Group B2. The NAS has classified carbon tetrachloride as an animal carcinogen. EPA has classified carbon tetrachloride in EPA's Group B2; sufficient evidence in animals and inadequate evidence in humans. EPA has placed carbon tetrachloride in Regulatory Category I, based upon its demonstrated carcinogenic effects in animals.

1,2-Dichloroethane. 1,2-Dichloroethane has been placed in Regulatory Category I, based upon its carcinogenic effects in animals through ingestion exposure. In the NCI bioassay, 1,2-dichloroethane administered by gavage to rats and mice was shown to increase the incidence of several types of tumors. 1,2-Dichloroethane has not been shown to be carcinogenic through inhalation exposure in animals. The IARC have classified 1,2-dichloroethane in Group B2; sufficient evidence of carcinogenicity in animals. EPA has classified 1,2-dichloroethane in EPA's Group B2; sufficient evidence in animals and inadequate evidence in humans.

Trichloroethylene. Six completed studies investigating the carcinogenic potential of trichloroethylene have been carried out. Two of these studies revealed significant increases in the incidence of liver tumors among both sexes of $B_6C_3F_1$ mice. Several of the remaining studies were technically flawed and the data cannot be used, and the remainder of the studies reported no evidence of carcinogenicity. A recent study (Henschler, et al., 1984) concluded that trichloroethylene containing epichlorohydrin and epoxybutane causes tumors in test animals, but that

purified trichloroethylene was not carcinogenic in ICR/HA mice. However, the Henschler study used mice that are known to be less responsive to hepatocellular carcinomas than the mice in several of the other studies. Therefore, EPA is not relying only on this study in drawing its conclusions regarding carcinogenicity. Trichloroethylene has exhibited DNA binding in short-term test systems.

There is disagreement in the scientific community about the relevance of mouse liver tumors as indicators of human cancer risk. Several strains of laboratory mice appear to develop a high and variable proportion of liver tumors with or without exposure to the chemicals. This may indicate that those mouse livers contain a signficant proportion of initiated tumor cells which do not appear to be present in human liver or it may indicate bias in the test protocol currently used by the National Toxicology Program (corn oil gavage). Certain scientists believe that the increased incidence of mouse liver tumors should be treated in the same manner as the increased incidence of tumors at any other rodent organ site, while others believe that mouse liver tumors are a spurious situation which is not relevant to human hazard.

The EPA proposed guidelines for carcinogen risk assessment (49 FR 46294) examined the relationship of mouse liver tumors to human hazard and concluded that "the mouse-liver-only tumor response, when other conditions for a classification of 'sufficient' evidence in animal studies are met, should be considered as 'sufficient' evidence of carcinogenicity with the understanding that this classification could be changed to 'limited' if warranted when a number of factors such as the following are observed: the occurrence of tumors only in the highest dose group and/or only at the end of the study; no substantial dose-related increase in the proportion of tumors that are malignant; the occurrence of tumors that are predominantly benign, showing no evidence of metasteses or invasion; no dose-related shortening of the time to the appearance of tumors; negative or inconclusive results from a spectrum of short-term tests for mutagenic activity; the occurrence of excess tumors only in a single sex".

The IARC stated that substances should be classified as having limited evidence of carcinogenicity if the studies involve a single species or experiment, are restricted by inadequate protocols and, in the past, have been difficult to classify as malignant by histological criteria alone (e.g., lung and liver tumors in mice).

The Office of Science and Technology Policy's report on chemical carcinogens (50 FR 10372) stated that,

> Generally, there is consensus that the mouse liver model in principle does have significance in terms of human risk, but unambiguous diagnosis between "benign" or "hyperplastic" liver nodules and malignant neoplasia remains elusive and there is no apparent scientific consensus. A recent review of the issue has emphasized the need for judgment on a case-by-case basis and the possible relevance of other toxicological information.

Based upon the EPA guidelines, EPA's Risk Assessment Forum classified trichloroethylene in Group B2; sufficient animal evidence of carcinogenicity and inadequate human evidence. As noted above, the EPA guidelines regard mouse liver tumors as sufficient evidence unless downgraded by other factors. EPA concluded that these other factors were not present for trichloroethylene and thus the compound was classified as having sufficient evidence of carcinogenicity. The NAS has classified trichloroethylene as an animal carcinogen.

EPA's Science Advisory Board (SAB) examined the toxicology of trichloroethylene and its ranking under the IARC criteria. The majority of the Committee members felt that the compound should be classified in IARC Category 3 (compound cannot be classified as to its carcinogenicity for humans), while one member felt that IARC Category 2B (probable human carcinogen) was more appropriate. The Committee concluded that, "a definitive statement on the carcinogenicity of the compound cannot be made by this Committee at this time because the interpretation of male mouse hepatocellular carcinomas is uncertain and the animal evidence is limited at this time".

EPA is conservatively classifying trichloroethylene in Regulatory Category I, based upon the positive evidence of liver tumors in $B_6C_3F_1$ mice, as well as malignant lymphomas in mice, pulmonary adenocarcinomas in mice, mutagenicity and binding with DNA, which has resulted in EPA's Risk Assessment Forum's classification of the compound in EPA's Group B2. The evidence for Category I ranking for trichloroethylene is weaker than for the other chemicals included in that group.

Tetrachloroethylene. The principal effect in animals from acute exposure to tetrachloroethylene is on the central nervous system. Central nervous system effects include depression, ataxia and respiratory cardiac arrest. Short-term/subchronic effects in animals are manifest principally as damage to the liver and kidney, while chronic effects also include liver and kidney damage, as well as central nervous effects. In humans, central nervous system depression and hepatic toxicity are also the principal effects exhibited from exposure to tetrachloroethylene.

The classification of tetrachloroethylene for carcinogenicity is based upon the results of several studies, including: (1) The NCI bioassay (1977) in which tetrachloroethylene (administered by gavage) increased the incidence of hepatocellular carcinomas in both sexes of $B_6C_3F_1$ mice, but not in rats. Due to high level of mortality among the rats, these data are not considered adequate. Several repeat studies were carried out; however data from these studies are undergoing audit by the NTP, (2) the draft report of the recently completed NTP bioassay (1985) in which tetrachloroethylene, administered through inhalation, was shown to induce carcinogenic effects in both rats and mice under the test conditions. The bioassay demonstrated an increased incidence of mononuclear cell leukemias in male and female rats and rare renal cell neoplasms in male rats. In mice, increased incidences of hepatocellular adenomas and carcinomas in males and hepatocellular carcinomas in females were seen; (3) several studies through inhalation and intraperitoneal exposure have produced negative results; and (4) mixed results have been obtained from a number of short-term studies designed to evaluate mutagenic potential. Tetrachloroethylene has not been shown to exhibit DNA binding in short-term studies.

EPA's Risk Assessment Forum, classified tetrachloroethylene in Group C, according to the EPA guidelines. Group C is used for agents with limited evidence of carcinogenicity in animals in the absence of human data. This classification was based upon the positive results from the NCI gavage bioassay and the inconclusive mutagenicity data. However, the new NTP rat and mice inhalation bioassay has since been completed, demonstrating a positive carcinogenic response in both species. Based upon this evidence and the positive carcinogenic evidence in mice by gavage (NCI, 1977), EPA has elevated the overall evidence of carcinogenicity to the "sufficient" category, Group B2.

The SAB examined the toxicology of tetrachloroethylene and the majority of the members of the SAB concluded that there was insufficient evidence to

classify tetrachloroethylene as a probable human carcinogen and that according to the IARC criteria the chemical belongs in Group 3. One member of the Committee agreed with the classification but felt that the compound "almost belongs" in Group 2B. This classification was carried out before the results of the NTP inhalation bioassay became available. The IARC had previously concluded that tetrachloroethylene has limited evidence of carcinogenicity in animals and inadequate evidence in humans and have classified the compound in Group 3; however IARC did not have the results of the NTP inhalation bioassay.

In summary, tetrachloroethylene has been classified in Regulatory Category I based upon the available data which have shown sufficient evidence of carcinogenicity in animals. This classification considers the new NTP cancer bioassay as well as other available data. As explained above, EPA is not promulgating an RMCL for tetrachloroethylene at this time. Rather, EPA is soliciting comments on the NTP bioassay.

1,1-Dichloroethylene. 1,1-Dichloroethylene has been shown to exhibit liver and kidney damage in animals from high dose exposure. Other acute and chronic effects include central nervous system depression and sensitization of the heart.

1,1-Dichloroethylene has been classified in Regulatory Category II. This classification is based upon an evaluation of the data involving over a dozen long-term animal studies, one short-term initiator/promotor assay and a series of short-term tests designed to evaluate mutagenic potential. The positive results have been reported in the following studies: (1) Kidney adenocarcinomas in mice and mammary tumors in rats and mice following inhalation exposure (Maltoni, 1985, in press); and (2) activity as an initiator in mice. Negative results have been reported in approximately a dozen studies involving exposure via inhalation, gavage and oral exposure via drinking water.

Short-term tests evaluating mutagenic potential have shown positive responses for DNA alkylation, repair and synthesis and negative results for cell culture tests. The IARC have concluded that there is sufficient evidence for activity in short-term tests.

The SAB examined the toxicology of 1,1-dichloroethylene and agreed with EPA that 1,1-dichloroethylene should be classified in Group 3, according to the IARC criteria. The SAB also recommended that the Agency attempt to verify the results of the Maltoni, *et al.*, 1977 study. The SAB did not review the results of the final Maltoni, *et al.*, inhalation study in this analysis since the data were not peer reviewed or published at the time. However, the SAB was critical of the carcinogenic risk estimates for 1,1-dichloroethylene, based upon the final Maltoni, *et al.*, inhalation data, stating that the uncertainties regarding the values needed to be better articulated.

EPA has classified 1,1-dichloroethylene in EPA's Group C, based upon the negative NCI bioassay, marginal results from inhalation exposure in mice and rats, activity as an initiator in mice and the mutagenic potential of the compuund. EPA believes that due to the mutagenic potential of the compound, the positive results in several animal studies and the compound's structural similarity to vinyl chloride there is a sufficient basis to regulate it in Category II rather than Category III.

1,1,1-Trichloroethane. The principal non-carcinogenic effects from exposure to 1,1,1-trichloroethane in animals and humans are depression of the central nervous system, increase in liver weight and cardiovascular changes.

1,1,1-Trichloroethane has been classified in Regulatory Category III (inadequate evidence of carcinogenicity in animals). This classification was based upon the results of two animals bioassays by the NCI. The first bioassay was completed in 1977 and consisted of exposure of mice and rats to 1,1,1-trichloroethane through corn oil gavage. Only 3 percent of the animals survived to the end of the experiment and thus it was concluded that carcinogenicity could not be determined from this study. In the second carcinogenesis bioassay, preliminary results showed an increased incidence of hepatocellular carcinomas in mice but not in rats. These initial results have been questioned and the study is presently being audited.

1,1,1-Trichloroethane has shown mixed results in mutagenicity studies. The compound was not shown to be mutagenic in studies using yeast as an indicator organism, while both positive and negative results were reported in mutagenicity using various *Salmonella typhimurium* strains. 1,1,1-Trichloroethane has been shown to exhibit minimal evidence of DNA binding in test systems.

The IARC have classified 1,1,1-trichloroethane in Group 3; inadequate evidence of carcinogenicity in animals. EPA has concluded that there are insufficient data to classify 1,1,1-trichloroethane as a probable or possible human carcinogen, based upon the results of the NCI biassays. Thus, 1,1,1-trichloroethane has been classified in EPA's Group D and Regulatory Category III.

p-Dichlorobenzene. p-Dichlorobenzene has been shown to exhibit non-carcinogenic adverse effects in animals, including liver and kidney damage, porphyria, and splenic weight changes. In humans, exposure to dichlorobenzenes has been reported to result in anorexia, liver effects and blood dyscrasias.

p-Dichlorobenzene has been classified in Regulatory Category III (inadequate evidence of carcinogenicity to humans). p-Dichlorobenzene has not been shown to be carcinogenic to animals or humans. Several animal studies have shown negative results for the compound, including a bioassay undertaken by the NTP in which p-dichlorobenzene was administered by gavage to both sexes of mice and to female rats. The draft results showed no evidence of carcinogenicity from exposure to the compound.

p-Dichlorobenzene has not been found to be mutagenic when tested in the *Salmonella typhimurium* or *E. coli* systems. However, the compound has been shown to induce abnormal mitotic division in higher plants.

EPA has concluded that p-dichlorobenzene should be classified in EPA's Group D and Regulatory Category III based upon the negative results of the carcinogenicity studies.

4. Final RMCLs

The following provides a summary and basis for the final RMCLs for each VOC, based upon the three-category approach.

Category I Contaminants

The RMCLs for Category I contaminants (known or probable human carcinogens) are set at zero, using the same approach as was outlined in the June 12, 1984, RMCL proposal. Thus, final RMCLs for the following substances considered to be known or probable human carcinogens are "zero": benzene, vinyl chloride, carbon tetrachloride, 1,2-dichloroethane and trichloroethylene.

Category II Contaminants

The RMCLs for Category II contaminants (equivocal evidence of carcinogenicity) are set based upon chronic toxicity data with an additional margin of safety, or upon lifetime risk calculations if chronic toxicity data are not available. For 1,1-dichloroethylene, EPA is setting the RMCL based upon chronic toxicity data, primarily liver effects observed in animal studies. The

RMCL is based upon the ADI divided by an extra factor of 10 to account for the possible carcinogenicity of the compound and considering 20 percent drinking water contribution. The AADI in the June 12 proposal for 1,1-dichloroethylene was 350 μg/l, based upon an animal study in which liver effects were noted. Applying an extra factor of 10, and considering 20 percent exposure from drinking water, a final RMCL of 7 μg/l has been determined. An extra factor of 10 was applied because EPA believes that an additional order of magnitude is appropriate for this chemical. This is because of the conflicting bioassay data and the structural similarity to vinyl chloride. Thus, EPA believes that these data cannot be dismissed and is accounting for these data by applying an additional order of magnitude uncertainty factor.

Category III Contaminants

The RMCLs for Category III contaminants (non-carcinogens) are determined based upon chronic toxicity data. The AADI considering 20 percent drinking water contribution is the basis for the RMCLs for these contaminants. For 1,1,1-trichloroethane, the final RMCL is 200 μg/l, as proposed on June 12, 1984. For p-dichlorobenzene, the final RMCL is 750 μg/l, as proposed on June 12, 1984.

Table 6 summarizes the final RMCLs for the VOCs. In the judgment of the Administrator, the RMCLs at these levels prevent known and anticipated adverse effects with a margin of safety.

TABLE 6.—FINAL RMCLS FOR THE VOCS

Compound [1]	RMCL
Benzene	zero
Vinyl chloride	zero
Carbon tetrachloride	zero
1,2-Dichloroethane	zero
Trichloroethylene	zero
1,1-Dichloroethylene	7 μg/l
1,1,1-Trichloroethane	200 μg/l
p-Dichlorobenzene	750 μg/l

[1] A final RMCL will be published for tetrachloroethylene after the close of the 45-day comment period, to allow for the public comments on the new data.

5. Effective Dates

The final RMCLs are effective December 13, 1985. This date is 30 days after the publication of this notice. However, as explained above, the RMCLs are only health goals used by EPA in determining maximum contaminant levels.

V. Public Docket/References

All supporting materials pertinent to the development of this final rule are included in the public dockets located at EPA headquarters, Washington, D.C. The two public dockets (i.e., RMCL rulemaking docket-closed-and the MCL/Monitoring docket) are available to the public and the public should contact the Drinking Water Regulations Docket Manager for access. Materials in the public docket include such documents as the following:

- Public comments on the ANPRM and Proposed Rulemaking for RMCLs.
- Transcripts of the April 26, 1982, and August 6, 1984 public meeting.
- Report and background material for the four public workshops, Summer 1982.
- Transcripts and meeting of NDWAC meetings.
- Summaries of meetings, telephone calls from outside EPA.
- Letters to/from the public.
- Technical reports.
- Other supporting materials.

VI. Regulatory Analyses

The promulgation of an RMCL is different than the proposal of an MCL in that an RMCL is, by law, to be based only on health and safety considerations, while an MCL takes feasibility and cost into consideration. Therefore, this RMCL notice does not include an analysis of the economic impact on various possible MCLs. However, the Agency has analyzed the probable impact of the various alternatives, and this is reported in the MCL proposal.

The report includes an analysis of the impact of the various alternatives on water supply industry vis-a-vis capital costs of technology, operating and maintenance costs and the feasibility of financing new treatment. Additionally, impact on the consumer and on the nation as a whole is presented.

Under the Regulatory Flexibility Act, 5 USC 601 et seq., I certify that this action will not have a significant impact on a substantial number of small entities. This action will have no economic impact in and of itself because this a non-enforceable health goal.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This action does constitute a "major" regulatory action because it will not have a major financial or adverse impact on the community and it is a non-enforceable action. This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

This rule contains no information collection requirements under the provision of the Paperwork Reduction Act of 1980 (44 USC 3501 *et seq.*).

List of Subjects in 40 CFR 141

Chemicals, intergovernmental relations, radiation protection, recording and recordkeeping requirements, water supply.

Dated: October 10, 1985.

Lee Thomas,

Administrator.

Appendix A. Summary of Comments

The following is a summary and discussion of the principal comments to EPA's proposed RMCLs for VOCs in drinking water and EPA's responses to them. A more detailed response to comments on the specific contaminants is contained in the background document, "Summary of Comments and Responses on **Federal Register** Notices on Volatile Synthetic Organic Chemicals in Drinking Water". In its June 12, 1984, Proposed Rulemaking, EPA specifically asked for comments on the following nine questions.

1. How strong should the scientific evidence be to justify regulating a substance, particularly for carcinogenicity?

2. How should evidence of mouse liver tumors be weighed? If evidence is limited to mouse liver tumors, is that sufficient evidence to warrant regulating that substance as a carcinogen? Conversely, what would be the scientific basis for giving mouse liver tumors less weight in the evaluation of the potential for human carcinogenicity?

3. For non-carcinogens, is the approach used for computing the AADIs scientifically acceptable? Is providing for an assumed contribution of 20 percent from drinking water appropriate when more precise data are not available?

4. Should RMCLs for carcinogens be set at zero? If RMCLs are set at zero, what guidance, if any, should be provided on the actually attainable target levels in drinking water?

5. Should RMCLs for carcinogens be set at the analytical detection limit? What would this be for each VOC considered in this proposal?

6. Should setting RMCLs for carcinogens be established at a non-zero level based upon negligible risk determinations? What non-zero level and upon what basis? Which model and which assumptions? Does an incremental lifetime risk level of 10^{-6} represent a virtually non-existent or negligible risk? Should higher or lower risk rates be considered? Would another level be more representative yet meet the needs for practical implementation of the SDWA? Would use of the linearized multi-stage model in the non-

zero RMCL calculations meet the Congressional intent to incorporate a margin of safety into the RMCLs?

7. Should a range of finite risk levels for each RMCL be selected such as 10^{-5} to 10^{-6} instead of zero or a single value?

8. How should the degree of evidence of potential carcinogenicity be factored into the RMCL determinations? It there is sufficient experimental evidence of human carcinogenicity, should the RMCL be either zero or the one in one million risk equivalent, or some other calculated value? Should the RMCL be set at a higher concentration and higher nominal risk (to indirectly reflect less concern) as the strength of evidence of carcinogenicity is reduced? For example, if there is only sufficient evidence of animal carcinogenicity, should the RMCL be in the 10^{-5} up to the 10^{-4} risk range? If less than "limited evidence" is available, should the RMCL be determined based upon and ADI calculation?

9. Should an RMCL and an MCL be set for total VOCs to address multiple exposure to VOC's? On what basis?

In all, EPA received 95 public comments; 19 from water utilities, 3 from water utility associations, 22 from industry, 13 from industry associations, 10 from State governments, 11 from public interest groups, 8 from private citizens and 7 from other groups including federal government agencies and academic institutions. The following discussion summarizes comments received on the proposed regulations and the Agency's responses to those comments.

A. Specific Questions Posed in Federal Register Notice

1. Strength of Evidence of Carcinogenicity (Questions 1 and 8 from the Federal Register notice RMCL proposal)

Comments: Eighteen comments were received which addressed how strong the strength of evidence should be to justify regulating a substance. Thirteen commenters suggested that strength of evidence should be used to determine which chemicals should be regulated and five of these commenters stated that EPA should establish minimum criteria for regulating a substance as a carcinogen, based upon the IARC criteria. Four of the commenters who addressed the IARC criteria stated that EPA should not regulate a substance for carcinogenicity if IARC has classified the compound in Group III and one commenter suggested that EPA could use the IARC classification to set RMCLs which incorporate strength of evidence, i.e., set RMCLs at zero for known carcinogens and at varying risk levels based upon the strength of animal carcinogenicity data.

Seven commenters suggested that minimum criteria for carcinogenicity should be set based upon an evaluation of the available data. One commenter said that a positive carcinogenic response in one animal species in a properly conducted test should be considered sufficient evidence to regulate a compound as a carcinogen, while five commenters stated that EPA should not regulate a chemical for carcinogenicity where there is only limited evidence of carcinogenicity. One commenter suggested that EPA should regulate a substance for carcinogenicity only if it has demonstrated a positive response in one or more epidemiological studies or in animal bioassays in two or more species.

Several commenters stated that a conservative approach should be taken where even sparse or limited evidence should be considered as indicative of pssible carcinogenicity and the compound should be regulated, while several other commenters said that a compound should not be regulated if there is substantial doubt as to whether it poses a significant risk to humans.

One commenter noted that it is impossible to draw a sharp line between carcinogens and non-carcinogens as there is no such thing as a non-carcinogen, only compounds which have not been tested for carcinogenicity. An additional comment addressed the significance of positive versus negative evidence, stating that positive evidence in a well-conducted study should outweigh negative evidence.

A comment was received which suggested that when evidence exists that a VOC may be harmful to health but evidence is sparse or inconclusive, the evidence should still be used in decisionmaking, providing the NAS agrees on the reasonableness of the judgment. If substantial doubt exists, this commenter suggested that EPA not set an RMCL. Several comments were received which questioned the decision to classify certain of the VOCs as carcinogens. These comments are discussed in the background document "Summary of Comments and EPA Responses on Federal Register Notices on Volatile Organic Chemicals in Drinking Water". One commenter felt that EPA's decision to classify several of the chemicals (unspecified) as carcinogens is questionable, due to the limited evidence of carcinogenic effects, the fact that these chemicals are not genotoxic and that the metabolites are the carcinogens.

Six commenters suggested schemes whereby RMCLs would be set at varying risk levels based upon the strength of evidence of carcinogenicity. One commenter noted that setting RMCLs at zero for human carcinogens, at a 10^{-6} risk level for animal carcinogens and at a 10^{-5} level where limited evidence of animal carcinogenicity exists is appropriate, while another commenter suggested a similar scheme with the inclusion of another category for those chemicals with limited evidence of human carcinogenicity. One comment was received which said that RMCLs should be set at a 10^{-6} risk level for known or suspect carcinogens and at a 10^{-5} risk level for compounds with limited evidence of carcinogenicity, while another commenter suggested the same strategy with a risk range of 10^{-5} to 10^{-6} for known carcinogens and 10^{-4} to 10^{-5} for compounds with limited evidence. A commenter noted a scheme in which RMCLs for known human carcinogens would be set at a 10^{-6} risk level, suspect human and known animal carcinogens at a 10^{-5} level and suspect animal carcinogens based upon chronic toxicity. An additional commenter stated a strategy of setting RMCLs for compounds with sufficient evidence of human carcinogenicity at a risk level of 10^{-6}, a risk range of 10^{-5} to 10^{-6} for compounds with sufficient evidence of animal carcinogenicity and a range of 10^{-4} to 10^{-5} for compounds with more limited evidence of animal carcinogenicity.

One commenter noted that strength of evidence should not be factored in the RMCLs and another commenter suggested setting non-zero RMCLs for all carcinogens at the same risk level, regardless of the amount of evidence of carcinogenicity.

One comment was received in which an alternate approach to setting RMCLs based on strength of evidence of carcinogenicity was proposed; this approach consisted of assigning letter scores to each chemical based upon the quantitative and qualitative evidence of carcinogenicity and assigning arbitrary concentration levels to each score. An AADI would be calculated for each chemical and the AADI would be compared to the arbitrary concentration level and the lower value would be used as the RMCL.

Response: EPA believes that all of the available scientific evidence should be used to determine whether a compound should be regulated and the basis for the regulation. A qualitative evaluation of the available data is carried out in order to determine the strength of evidence of carcinogenicity or other adverse health

effects. EPA then makes the decision on whether or not to regulate based upon a consideration of the potential for the compound to cause adverse health effects and the likelihood of the compound being found in drinking water.

The alternative approach provided by the commenter in which letter scores are assigned to each chemical is a valid method for ranking chemicals for further action considering priority to relative risk. However, such an approach does not appear to be the method of choice for setting RMCLs, as the concentration levels assigned to the number scores are purely arbitrary. The approach does not appear to satisfy the requirement that the RMCL be set at the no-effect level incorporating an adequate margin of safety.

EPA agrees with the commenters who stated that a conservative approach should be taken with regard to the regulation of chemicals with limited evidence of carcinogenicity or other adverse health effects. This approach is consistent with the intent of the SDWA that EPA should err on the side of safety in setting the regulations and that conclusive proof of human risk is not needed in order to regulate a substance. The legislative history states, "Because of the essentially preventive purpose of the legislation, the vast number of contaminants which may need to be regulated, and the limited amount of knowledge presently available on the health effects of various contaminants in drinking water, the Committee did not intend to require conclusive proof that any contaminant *will* cause adverse health effects as a condition for regulation of a as suspect contaminant. Rather, all that is required is that the Administrator make a reasoned and plausible judgment that a contaminant may have such an effect". The legislative history continues to say that, "the contaminant need not have the adverse effect directly in order for the Administrator to regulate it as a primary contaminant. If it is a precursor to a contaminant which may have such effect or if it may contribute to such effect, the contaminant should be controlled under primary regulations". H.R. 93–1185, 93rd Cong. 2d sess. at 10 (1974).

EPA agrees with the comments received stating that minimum criteria should be established for regulating substances as carcinogens. EPA has established criteria for regulating substances as carcinogens based upon the EPA Proposed Guidelines for Carcinogen Risk Assessment (49 FR 46294). These guidelines are directly derived from the IARC criteria. The EPA guidelines provide a classification system for dividing chemicals based on their strength of evidence of carcinogenicity. The classification scheme divides chemicals into five categories: Group A, human carcinogen; Group B, probable human carcinogen; Group C, possible human carcinogen; Group D, not classified; Group E, no evidence of carcinogenicity to humans. The IARC criteria divides chemicals into three categories: Group 1, chemical is carcinogenic to humans; Group 2, chemcial is probably carcinogenic to humans; Group 3, chemical cannot be classified as to its carcinogenicity to humans. The major difference between the two classification schemes is that IARC does not distinguish between those chemicals with inadequate evidence of carcinogenicity and those chemicals with no evidence of carcinogenicity, while the EPA scheme does.

EPA does not believe that it is appropriate to apply a strict rule in which chemicals are not regulated for carcinogenicity if IARC has classified them in Group 3. The IARC classifications are several years old and new data which was not available at the time of categorization may indicate possible carcinogenic effects for a compound. EPA believes that all available data should be considered in the analysis. Both positive and negative evidence is weighed together with the quality of the study, and the many case-specific factors which are present in evaluating each contaminant and study. Depending on the strength of evidence, negative evidence may outweigh positive evidence or vice versa. In addition, the IARC Group 3 includes those chemicals with inadequate evidence of carcinogenicity and those chemicals with no evidence of carcinogenicity. Thus, a chemical could be classified in Group 3 because it was never tested for carcinogenicity or because it has shown inconclusive results, and not necessarily because it has shown negative results in animal studies.

The EPA classification scheme distinguishes between chemicals with inadequate evidence and no evidence of carcinogenicity; Group D (inadequate evidence) is defined as follows: "because of major qualitative or quantitative limitations, the studies cannot be interpreted as showing either the presence or absence of a carcinogenic effect". Group E, (no evidence) indicates that "there is no increased incidence of neoplasms in at least two well-designed and well-conducted animal studies in different species". EPA believes that this scheme helps to differentitate between those chemicals which have been tested and those which have shown negative results.

The minimum level of evidence for a compound to be regulated as a probable human carcinogen (EPA's Group B2) consists of animal evidence which is considered to be sufficient, i.e., evidence which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains or in multiple experiments, or to an unusual degree with regard to incidence, site of tumor, or age at onset. Therefore, EPA agrees with those commenters who would classify as carcinogens those contaminants with positive results in one or more animal studies. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests or on chemical structure. This is consistent with the view held by the NAS and others that animal studies may be extrapolated to man.

For a compound to be considered an "equivocal" carcinogen (EPA's Group C), the evidence has been determined to be limited using EPA's proposed guidelines for carcinogenic risk assessment definition of "limited" evidence as follows: "the data suggest a carcinogenic effect but are limited because: (a) The studies involve a single species, strain, or experiment, or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting, or (c) an increase in the incidence of benign tumors only."

EPA will promulgate RMCLs at zero for those substances classified in Groups A and B (vinyl chloride, benzene, carbon tetrachloride, 1,2-dichloroethane and trichloroethylene). This is based upon the same philosophy that was followed in the RMCL proposal; i.e., that RMCLs for chemicals with sufficient evidence of carcinogenicity should be set at zero. The basis was that the RMCLs are to be set at a level which would not result in adverse health effects with an adequate margin of safety. The legislative history of the SDWA states that if there is no safe threshold for a contaminant, the RMCL should be set at zero. EPA believes that for those chemicals in Group A or B (human carcinogen or probable human carcinogen), there is sufficient evidence of carcinogenicity to warrant setting the RMCLs at zero.

For the substance classified in Group C (1,1-dichloroethylene), the RMCL will be promulgated at a non-zero level, based upon chronic toxicity data (the ADI with an additional margin of safety). If chronic toxicity data were not available, the RMCL would be based upon cancer risk (the 10^{-5} or 10^{-6} risk level). The chemicals classified in Group C do not have sufficient evidence to be classified as carcinogens, yet there are some data to indicate possible concern. Thus, these substances should be treated more conservatively than non-carcinogens, yet less conservatively than those chemicals classified as probable human carcinogens. Even though insufficient data on potential carcinogenicity are available, the RMCL should still be set at a level which would represent and extremely low nominal risk. EPA believes that either the risk calculation approach or the ADI approach with an additional factor provide an RMCL which is very conservative to protect against potential adverse effects. In essence, setting a more conservative RMCL for these contaminants provides an appropriate additional margin of safety.

RMCLs will be promulgated based upon chronic toxicity (the ADI) for those substances classified in Groups D and E (1,1,1-trichloroethane and p-dichlorobenzene). Those chemicals classified in Groups D and E have inadequate evidence or no evidence of carcinogenicity to humans. EPA believes that the approach followed in the RMCL proposal for non-carcinogens (i.e., set the RMCL based upon chronic toxicity data) is the best method for establishing the "no effect" level with an adequate margin of safety for threshold toxicants. This method follows the state-of-the-art concepts in toxicology and is generally accepted by the scientific community at large.

In adopting this classification scheme and in categorizing contaminants, EPA must make science policy judgments which draw heavily on its expertise and experience. The Agency believes its scheme and the lines it draws between classes of carcinogens are based on scientific ground well-trod by IARC, NAS, and OSTP. As stated by a member of the SAB, "The decision of CAG to utilize the IARC classification system for carcinogenicity has been supported and encouraged by the SAB on several previous occasions, and when combined with the weight of evidence as described in Dr. Paynter's Standard Evaluation Procedure document, represents a logical and scientifically defendable course of action for the Agency. . . . It may be useful, for example, to consider the Safe Drinking Water Committee approach for Category 3 agents (ADI with safety factor) and to reserve the Weibull extrapolation method for Category I and II agents." The adoption of the scheme for regulatory purposes under the Safe Drinking Water Act provides a strong scientific basis for regulation and clear guidelines for Agency decisionmaking. Highly complex toxicological judgments must still be made in categorizing contaminants in the EPA scheme and in weighing the different types of evidence and their strength.

2. Mouse Liver Tumors

Comments: Four commenters suggested that an increased incidence of mouse liver tumors should not be used as a basis to regulate a substance as a human carcinogen. The rationale was that the induction of mouse liver tumors is not relevant to human hazard, as the mouse liver is known to develop spontaneous tumors with or without the application of the chemical. These commenters felt that the mouse is not a good model for effects in humans due to the development of spontaneous tumors which appear to be affected by sex, strain, diet and endocrine factors of the mice. In addition, several of these commenters stated that scientific consensus is that mouse liver tumors are not relevant to human hazard and cited the conclusions of the report of the Nutrition Foundation Expert Advisory Committee that, ". . . therefore, the relevance to human populations, at least in these regions, of such enhancement of spontaneous tumor incidences in the mouse is questionable".

Six commenters felt that the EPA should not dismiss an increased incidence of mouse liver tumors in assessing the potential carcinogenic risk. Two of the commenters stated that positive results in liver tumors in mice should be considered "limited" evidence of carcinogenicity or the weakest evidence of carcinogenicity in a continuum of strength of evidence. The other four comments suggested that EPA should take a conservative approach and consider mouse liver tumors as a predictor of human risk. Several of these commenters noted that studies have shown that most chemicals which induce liver tumors in mice also cause neoplasms in other rodents and in other tissues of mice. These commenters felt that mouse liver tumors should be considered as a strong indicator of carcinogenic potential, but other available evidence should also be factored in when making a determination. One of these commenters noted that mouse liver tumors fall under potential risks covered by the SDWA, as EPA should err on the side of caution.

One commenter noted that under certain conditions, a tumor response in the mouse liver should be given less weight and there would be little cause for restricting the chemical. These conditions are: (1) If the compound produces tumors only in the mouse liver, particularly if the tumors are benign neoplasms, (2) if the compound fails to covalently bind to cellular macromolecules, and (3) if the compound fails to show activity (negative results) in well-validated tests for DNA damage. Another commenter felt that questionable weight should be given to mouse liver tumors and other species of animals should provide supportive evidence as a basis for VOC regulation.

Response: EPA believes that all available evidence should be used in the evaluation of a chemical for a possible carcinogenic risk. Mouse liver tumors should be considered and evaluated along with all other available evidence. EPA feels that it is not appropriate to completely discount such data.

The U.S. Office of Science and Technology Policy's report on chemical carcinogens (50 FR 10417) examined the biological significance and human relevance of mouse liver tumors. They concluded,

> Some scientists are certain that the mouse liver is overly sensitive and will respond to almost any toxic insult by developing cancer. Other scientists are just as certain that the mouse liver is a reliable indicator of carcinogenicity and as good a predictor of potential human risk as any indicator available. In one review, 61 of 85 chemicals (73%) that increased the incidence of liver tumors in mice also induced tumors in other tissues of mice and/or in rats. Some toxicologists believe that part of the problem stems from work on C_3H strains of mice where the background liver tumor incidence is high and false positive errors are possible. Generally, there is consensus that the mouse liver model in principle does have significance in terms of human risk, but unambiguous diagnosis between "benign" or "hyperplastic" liver nodules and malignant neoplasia remains elusive and there is no apparent scientific consensus. A recent review of this issue has emphasized the need for judgment on a case-by-case basis and the possible relevance of other toxicological information.

EPA endorses the OSTP findings.

EPA's proposed guidelines for carcinogen risk assessment (49 FR 46294) state that mouse liver tumors, when other considerations for classification as "sufficient" evidence of animal carcinogenicity are met, should be considered to be sufficient evidence of carcinogenicity with the

understanding that this classification could be changed to "limited" when a number of factors are found to be present. These factors include occurrence of tumors only in the highest dose group, no substantial dose-related increase in the proportion of tumors that are malignant, predominately benign tumors showing no evidence of metasteses, no-dose-related shortening of the time to the appearance of tumors, negative or inconclusive results from short-term tests from mutagenic activity and the occurrence of excess tumors only in a single sex. The EPA proposed guidelines consider chemicals in Group A (human carcinogen) and Group B (probable human carcinogen) to have "sufficient" evidence of carcinogenicity. Chemicals classified in both of these groups are placed in Regulatory Category I; known or probable human carcinogens for the purpose of setting the RMCL. Chemicals classified in Group C are considered to have "limited" evidence of carcinogenicity and are placed in Regulatory Category II; equivocal evidence of carcinogenicity.

EPA believes that it is reasonable to follow a conservative approach with regard to mouse liver tumors. The report by the Office of Science and Technology Policy concluded that there is consensus that the mouse liver model does have significance in terms of human risk and the EPA guidelines also concluded that mouse liver tumors should be considered as evidence of animal carcinogenicity. The EPA guidelines examine additional factors which could result in the classification being changed to "limited", and thus allow for situations in which the mouse liver tumors should be given less weight depending on additional evidence. This approach is consistent with the legislative history of the SDWA which states that conclusive proof is not needed in order to regulate a substance; all that is required is that a judgment be made that a contaminant *may* have an adverse effect. The legislative history also notes that the SDWA is a preventive statute and EPA should err on the side of safety.

EPA agrees with the commenter who suggested that the presence of certain conditions, such as benign neoplasms, should result in giving less weight to a tumor response in the mouse liver. The EPA guidelines state that the presence of these sort of factors may result in changing the classification of the chemical from "sufficient" evidence of animal carcinogenicity to "limited" evidence. However, EPA does not agree with this commenter that there would thus be little cause for restricting the chemical. As discussed above, EPA believes that a preventive approach must be taken according to the SDWA.

Both trichloroethylene and tetrachloroethylene have shown an increase in mouse liver tumors and for both chemicals this evidence has been used to classify the chemicals in Group B2, according to the EPA classification system. For trichloroethylene, this was based upon the fact that an increase in mouse liver tumors was seen in two studies from exposure to trichloroethylene which was not associated with any of the factors discussed above. Thus, the mouse liver tumors are considered to be "sufficient" evidence of carcinogenicity. For tetrachloroethylene, mouse liver tumors were seen in two studies and mononuclear cell leukemias were noted in rats in one study. Thus, these results were considered "sufficient" evidence of carcinogenicity for tetrachloroethylene.

3. AADI Approach

Comments: Twenty-five comments were received which addressed the approach used for calculating the AADIs for non-carcinogens and/or the appropriateness of assuming a 20 percent contribution from drinking water. The majority of commenters (eighteen), basically agreed with the AADI approach. Several commenters agreed with the overall approach but suggested specific recommendations for changes. One commenter felt that there should be a requirement that both negative (no-observed-adverse-effect level (NOAEL)) response data and positive (low-observed-adverse-effect level (LOAEL)) response data be available within a narrow range while another commenter suggested that additional safety factors be employed for mutagens and teratogens. A comment was received which suggested that EPA should use the 10 kg child consuming 1 liter of water per day instead of the 70 kg adult consuming 2 liters of water per day as the basis for the calculations. A commenter stated that EPA's overall approach to calculating AADIs is basically sound but overly conservative in some of its assumptions, such as the assumption that the adult consumes 2 liters of water per day. This commenter felt that many ingested fluids either do not derive from drinking water or have been boiled so that much of the VOC content will have been driven off. One commenter agreed with the AADI approach, but felt several of the AADIs are too high. This commenter stated that it is inconsistent with EPA's definition of RMCLs to use the no-observed-adverse-effect level (NOAEL) instead of the no-observed-effect level (NOEL), and also inappropriate to use inhalation studies and studies of less than lifetime duration in calculating the AADIs. This commenter felt that when insufficient data are available, EPA may want to consider setting the RMCL at an arbitrary level.

Five commenters disagreed with the AADI approach. One commenter stated that the AADIs are too high when compared to the analytical detection limits and another commenter noted that AADIs could be used if people were exposed to only one contaminant at a time. A comment was received which said that EPA should base the AADIs upon the 10 kg child and EPA should also reevaluate the safety factors used. This commenter felt that safety factors of 10, 100 and 1000 are too arbitrary and a range of safety factors should be used depending on the quality and nature of the data. An additional commenter disagreed with the AADI approach because with animal tests divided by 10, 100 or 1000 and then reduced by 80 percent, a value lower than the calculated values could be used for RMCLs. A comment was received which stated that EPA has been overly conservative in computing certain of the AADIs and this commenter submitted a different approach to the calculation of AADIs.

On the question of EPA's use of a 20 percent drinking water contribution to the AADI, five commenters agreed with this approach while thirteen commenters disagreed. Of the comments received which agreed with a 20 percent contribution, four commenters felt that in the absence of experimental data 20 percent appears to be a reasonable approximation and one of these commenters suggested that if a substance accumulates to a high degree, a value as low as 1 percent contribution from drinking water should be used. One commenter stated that EPA should determine the precise contribution from food and air, and if drinking water is shown to be greater than 20 percent, the precise value should be used and if drinking water contributes less than 20 percent, 20 percent should be used.

Of the thirteen commenters who disagreed with the use of 20 percent, the majority noted that 20 percent is speculative and has not been justified. Two commenters stated that 20 percent is unduly conservative and one of these commenters suggested that RMCLs should be set at 100 percent of the AADI unless there are data to justify a lower level. An additional two comments were received which said that 20 percent

should be lowered in order to account for absorption through the skin and other intakes.

One commenter felt that the literature contains sufficient information for EPA to assess the actual contribution from inhalation and possibly oral exposure for some contaminants, and for pollutants lacking such information, an 80 percent to 90 percent correction may be justified. This was based upon a study which suggested that contaminated drinking water acting as a single source of contamination may contribute significantly to daily inhalation, oral and dermal burdens. A commenter suggested that the RMCL should be set based upon the AADI using a percentage of the total daily intake of 1 percent to 5 percent from drinking water if the toxicologic data meets some minimum criteria for completeness. Another commenter noted that if there are data which shows drinking water to be responsible for 20 percent of a person's VOC uptake, then 20 percent should be used. In the absence of such data, this commenter felt that it is more reasonable to attribute 50 percent of a person's intake to drinking water.

The National Drinking Water Advisory Council recommended that 20 percent contribution from drinking water is a reasonable value to use in setting the RMCLs for non-carcinogens in the absence of more definitive data. However, the Council stressed that EPA should work toward the improvement in the data base in these areas and should use actual data when available.

Response: EPA believes that the approach used for determining the AADIs follows state-of-the-art concepts in toxicology and is scientifically justified. The determination of the no-observed-adverse-effect level (NOAEL) from animal or human data and dividing this by an appropriate safety factor is well established and accepted in the scientific community. This approach is consistent with the SDWA which requires EPA to identify and regulate adverse effects and to prevent the occurrence of any known or anticipated adverse effect. Therefore, EPA rejects use of the no-observed-effect level in favor of the no-observed-adverse-effect level. EPA must also include an adequate margin of safety, unless there is no safe threshold for a contaminant.

The National Academy of Sciences (NAS) (*Drinking Water and Health*, Vol. I, 1977), used the ADI approach to determine health levels at which exposure to a chemical would not be anticipated to produce adverse health effects in humans. The NAS (*Drinking Water and Health*, Vol. I, 1977, pp. 803–804) recommended that the uncertainty factor should reflect the degree or amount of uncertainty when experimental data in animals are extrapolated to humans. They recommend that when the quality and quantity of data are high, the uncertainty should be low and that when data are inadequate or equivocal, the uncertainty factor should be larger. The NAS also suggested the following guidelines to be used in establishing uncertainty factors: uncertainty factor of 10 to be used with valid experimental results from studies on prolonged ingestion by man; uncertainty factor of 100 to be used with valid experimental results on long-term feeding studies on experimental animals, and uncertainty factor of 1000 to be used with scanty results on experimental animals (NAS, *Drinking Water and Health*, Vol. I, 1977). EPA has followed these guidelines in applying uncertainty factors in the derivation of the AADIs/DWELs.

EPA believes that the application of uncertainty factors following the NAS guidelines is a viable method for establishing a margin of safety which corresponds to the amount of data available. EPA agrees with the commenter who stated that a range of safety factors should be used depending on the quality and nature of the data, and EPA believes that the NAS guidelines establish such a range. EPA does not agree that safety factors of 10, 100 and 1,000 are too arbitrary; these safety factors have been established based on scientific precedent which has shown that order of magnitude safety factors have been protective. Regarding the suggestion that additional safety factors be employed for mutagens and teratogens, the NAS uncertainty factors relate to all types of non-carcinogenic data, including teratological effects. EPA considers all types of effects in the analysis of the available data to determine the uncertainty factor to be applied. Mutagenic effects are examined as a separate toxicological endpoint and also considered in the analysis of strength of evidence of carcinogenicity. In this regard, they play a role in determining the classification of the chemical according to the EPA guidelines.

In regard to the comment concerning negative (NOAEL) and positive (LOAEL) data, EPA uses all of the available dose-response data to determine the best study upon which to base the ADI. Ideally, EPA will use the NOAEL to determine the ADI, since the purpose of the ADI is to determine the level at which adverse health effects would *not* be observed. However, EPA believes that it is appropriate to use the LOAEL, when a NOAEL is not available, with the application of an additional uncertainty factor to account for the observed effects. It is not necessary that data show they are within a narrow range to protect against adverse effects. First, in many cases, fully complete data will not be available and the SDWA clearly contemplates regulation where there is sufficient evidence to identify an adverse effect through a NOAEL or a LOAEL. Second, even where complete data are available, some contaminants will have a LOAEL that is not within a narrow range of the LOAEL. Certainly, regulation of these contaminants posing an adverse effect is justified under the Act. For these reasons, EPA is justified using either a NOAEL or LOAEL and applying additional uncertainty factors for the LOAEL.

As stated above, EPA believes that all of the available data should be examined and a determination made of the most appropriate study upon which to base the ADI. Ideally, that study will be a lifetime study via ingestion. However, the ideal data base is rarely available and EPA uses the best available valid study, even if the study has limitations such as the route of exposure or the number of animals. EPA believes that the use of an additional uncertainty factor will account for the study's limitations and is the best method available for deriving the ADI. So, for example, while a drinking water study is preferred, an inhalation study may be useful for assessing drinking water effects and may be the basis for an RMCL if an additional uncertainty factor is employed. EPA feels that basing the ADI upon the best available scientific data is appropriate and rejects setting the RMCL at an arbitrary level, which has no basis in science.

EPA believes that it is reasonable to assume two liters per day for drinking water consumption. This value was used by the NAS in *Drinking Water and Health*, Vol. I, 1977 and has been used in subsequent volumes. According to the NAS (p. 11), "The average per capita water (liquid) consumption per day as calculated from a variety of nine different literature sources was 1.63 liters. . . . However, the larger volume of 2 liters/day was adopted as representing the intake of the majority of water consumers." The National Interim Primary Drinking Water Regulations also used a value of 2 liters of water per day, based upon the data which indicated that a tremendous variation in individual consumption exists, but that 2 liters per day constituted a high but reasonable average intake for an adult male.

In reference to the comment which stated that the AADIs are too high when compared to the analytical detection limits; the AADIs are numbers based upon the scientific data which indicate that level at which adverse health effects would not be anticipated over a lifetime exposure. The analytical detection limits are not health based numbers; they simply represent the current state-of-the art in analytical capabilities. Thus, EPA believes that it is not appropriate to compare these two values as they represent two different end-points.

EPA agrees with the commenter who noted that people are exposed to more than one contaminant and thus a conservative approach should be taken. However, EPA does not agree that AADIs should not be used, as the AADIs are calculated with a significant margin of safety built in.

The use of the 70 kg adult rather than the 10 kg child as the basis for the AADIs is considered appropriate, except in those instances where the child has been shown to be the more sensitive subpopulation for a given effect. In these cases, the 10 kg child will be the basis. The basis for the 70 kg adult is that the RMCLs are intended to be protective for a lifetime exposure and a 10 kg child is not exposed over a 70 year lifetime. Calculating AADIs on the basis of a child's body weight would not provide a meaningful measure of the effects over a lifetime exposure. EPA agrees with the commenter who stated, "while we agree that RMCLs should be targeted to protect sensitive members of the population, we believe it inappropriate to presume *a priori* that children are the sensitive subpopulation. Increased dose per unit of body weight should not be confused with truly increased sensitivity to a chemical. We support the use of *actual* sensitivity data to determine no observed adverse effect levels and to calculate ADIs." Commenters provided related reasons for rejecting ADI's based on children. EPA agrees with those commenters. EPA believes that by applying uncertainty factors in the calculations, the health effects numbers are sufficiently protective for all segments of the population.

EPA has discussed the comments' suggestions concerning specific AADIs and the alternative approach suggested for the calculation of AADIs in the background "Summary of Comments" document.

With respect to an assumed 20 percent contribution from drinking water, EPA is following the recommendations of the National Drinking Water Advisory Council and is applying a 20 percent relative source contribution factor in the absence of data indicating the actual contribution of the chemical from air, food and water. If there are data showing the precise contribution from food and air, EPA will use this data and factor it into the RMCL determination. EPA agrees with the recommendations of the National Drinking Water Advisory Council that further work is needed in this area and will continue to support efforts to better define the contributions from various media to overall exposure.

A 20 percent drinking water contribution was used in the National Interim Primary Drinking Water Regulations and by the NAS who used projections of 1 percent and 20 percent as illustrations of drinking water contribution. The NAS did not recommend a specific value for drinking water contribution. EPA has used a 20 percent drinking water contribution factor as a reasonable approximation of the actual exposure and recognizes that this value may somewhat either overestimate or underestimate the actual drinking water contribution. EPA does not believe that it is appropriate to set the RMCL at 100 percent of the ADI, as drinking water is not the sole contributor to total exposure, and using 100 percent of the ADI would underestimate the other sources of exposure. Because VOCs are high volume industrial chemicals, some of which are commonly used by consumers (e.g., benzene in gasoline) or appear in consumer products (e.g., 1,1,1-trichloroethane) is very likely that there will be exposure from other sources than drinking water. EPA also recognizes that dermal absorption may contribute to the overall exposure. However, EPA does not feel that the methodology is well enough developed to factor this specific exposure into the RMCL calculations. In addition, the application of the uncertainty factor and 20 percent drinking water contribution helps to take into account possible additive or synergistic effects and the possible high exposure portion of the population.

4. RMCLs for Carcinogens at Zero

Comments: Seventy-three commenters addressed the issue of whether RMCLs for carcinogens should be set at zero. Twenty-seven commenters said that the RMCLs for carcinogens should be set at zero, primarily based upon the House Report which stated that the RMCL for contaminants for which there is no safe threshold should be set at zero. In addition, many of these commenters stated that carcinogens should not be present in drinking water and the RMCLs as health based goals would demonstrate EPA's commitment to this philosophy. Two of these commenters presented strategies in which RMCLs were set at zero for known human carcinogens and at risk levels for compounds with more limited evidence of carcinogenicity. A commenter stated that those compounds with sufficient evidence of human or animal carcinogenicity should be set at zero, while those with substantial doubt as to carcinogenicity should be set at the ADI with an added safety factor. One commenter felt that RMCLs of zero should be set for all chemicals, non-carcinogens as well as carcinogens and another commenter noted that guidance on levels actually attainable is more appropriately provided in the context of the MCLs.

Forty-seven commenters stated that RMCLs for carcinogens should not be set at zero for any contaminant. The major reasons were that zero is not measurable or attainable and is scientifically undefinable. If was noted by several commenters that setting RMCLs at zero is counterproductive as it will project an unscientific image to the public, i.e., that zero concentration is achievable. In addition, several commenters suggested that RMCLs at zero will confuse and alarm the public and will be generally interpreted as being standards. These commenters generally felt that RMCLs should be workable levels which would provide actual guidance on levels attainable in public water systems.

The National Drinking Water Advisory Council recommended that RMCLs not be set at zero, as zero was not considered to provide a realistic/practical health goal for public water systems, because zero is undefinable in the analytical sense and unachievable. A minority of the members of Council felt that RMCLs for some, if not all, carcinogens should be set at zero since RMCLs are health goals, not practical, achievable levels, and as such should be set at zero to be consistent with the scientific community on the safety of exposure to carcinogens.

Responses: EPA has concluded that the RMCLs for probable human carcinogens (EPA's Group A or Group B) should be set at zero. This approach is consistent with the guidance provided in the House Report which stated that if there is no safe threshold for a contaminant, the RMCL should be set at zero. EPA believes that the zero level is necessary to prevent known or anticipated effects from human or probable human carcinogens including a margin of safety. No other margin of safety would be adequate since EPA

does not believe a threshold for carcinogens exists. Thus, there is likely to be some known or anticipated adverse effects at levels above zero.

EPA does not believe a zero RMCL is appropriate for chemicals with equivocal evidence of carcinogenicity. In setting the RMCL, EPA would be oversimplifying to treat contaminants with equivocal evidence of carcinogenicity the same as contaminants with sufficient evidence of carcinogenicity and that have not been shown to exhibit a threshold. To treat these contaminants as carcinogens is to ignore the equivocal evidence. Probability of an adverse effect is not a prerequisite for setting an RMCL which takes account the equivocal evidence. Legislative history provides that EPA is to regulate even where faced with uncertainty.

EPA does not agree with the comment that RMCLs of zero should be set for all chemicals. For those chemicals which have not demonstrated carcinogenic effects, the ADI approach is a well established method for determining the level at which adverse health effects would not be anticipated. This approach considers threshold evidence and is an appropriate technique for determining non-zero levels for non-carcinogens. Of course, a margin of safety is incorporated, which provides an additional measure of protection.

In response to the commenters who stated that RMCLs should be set at practical levels, rather than at zero, EPA believes that the MCLs reflect technological and economic feasibility, and the RMCLs purely reflect health considerations. The RMCLs are goals which may or may not be practically achievable and the practicality of these levels should be factored into the MCLs, not the RMCLs.

With regard to the concern that setting RMCLs at zero will alarm the general public and project an unscientific image, EPA believes that the public will be able to distinguish between RMCLs as goals and MCLs as enforceable standards and will not be alarmed at setting a goal of zero. RMCLs are only health goals to be used by EPA in setting the MCLs. Public water systems are not required to meet the RMCLs. EPA has emphasized in the rulemaking that zero is not a measurable level in scientific terms and will continue to emphasize this point to the public. That zero is not measurable or attainable is irrelevant to the purpose of setting RMCLs which is to set a health goal to prevent adverse effects with a margin of safety. Even if the public were to be alarmed or concerned at RMCLs set at zero, EPA would still choose RMCLs set at zero as most consistent with its statutory mandate, as explained above.

5. RMCLs for Carcinogens at the Analytical Detection Limit

Comment: One comment was received which suggested that RMCLs for carcinogens be set at the analytical detection limit. This commenter stated that he recommended that RMCLs represent the ideal; potable water free from harmful constituents. Because attainment of this level (zero) is impossible to validate, the RMCLs would be effectively established at the existing detection limit. One commenter stated that as a last resort an RMCL equal to or double the detection limit might be considered, while twenty-four commenters thought that RMCLs set at the analytical detection limit were not appropriate. The reasons given were that the detection limit has no relationship to health risk, is dependent on the technology of the time and is constantly changing. In addition, problems with interlaboratory variation were cited.

Response: EPA agrees with the majority of commenters that RMCLs for carcinogens should not be set at the analytical detection limit. The analytical detection limit is not based upon health risk. It is usually an extremely low number representing the lowest measurement above zero. However, the analytical detection limit is a moving target as the state-of-the-art in chemistry progresses and is very much dependent on the technology of the time.

RMCLs are not meant to be standards for public water systems to achieve; they are to be set by EPA based on health considerations alone. RMCLs are only promulgated by the Agency as health targets for the MCL rulemaking. In addition, RMCLs are to be set to prevent known and anticipated adverse effects to include a margin of safety; they are not to be set at analytical detection limits under the statute.

6. RMCLs for Carcinogens Based on Risk Calculations

Comments: Thirty-four comments were received which suggested that RMCLs for carcinogens should be established at a non-zero level based upon negligible risk determinations. The primary basis was that risk models provide a scientific means for assessing the risk to the human population from chemicals in drinking water and are sufficiently conservative to provide an ample margin of safety. The general risk range most often mentioned as a target level was one in a hundred thousand (10^{-5}) to one in a million (10^{-6}). Five commenters said that a (10^{-5}) level was appropriate while five commenters felt that a level of (10^{-6}) should be used. One commenter stated that if the potential human exposure is less than the best estimates of risk, the RMCL should be set a (10^{-6}) risk level, while if the potential human exposure exceeds this level of risk all data should be reviewed and an appropriate RMCL adapted. One commenter suggested that a one in a million *yearly* risk should be used with the upper 98th percentile of the probability distribution of the risk coefficient and another commenter stated that an annual risk of (10^{-5}) to (10^{-6}) is appropriate. Three comments were received which said that the upper and lower confidence limits as well as the best estimates should be provided for each risk estimate. Several commenters stated that the linearized multi-stage model overestimates the actual risk while one commenter noted that the multi-stage model is relatively conservative and protective. Another commenter suggested that linearized models be abandoned until more data are gathered on synergistic effects.

The National Drinking Water Advisory Council recommended that RMCLs for carcinogens be set at the (10^{-6}) risk level using a conservative risk model. This was based upon the premise that a one in a million excess risk rate presents a virtually negligible risk which should be socially acceptable. A minority of the members of the Council felt that RMCLs for carcinogens should not be set based upon a risk calculation approach, but set at zero, as discussed in Issue 4.

Responses: EPA has concluded that the RMCLs for known and probable carcinogens should be set at zero rather than based upon calculations of risk and a subjective judgment as to what is a negligible or acceptable risk. For known and probable carcinogens, zero best meets the direction of Congress that EPA set RMCLs to prevent known or anticipated effects with a margin of safety. For contaminants with equivocal evidence of carcinogenicity, a zero RMCL is not considered appropriate, as explained above. A risk estimate may be used to set a more conservative RMCL for these contaminants than would otherwise be established considering non-carcinogenic endpoints. EPA is using risk estimates for these contaminants to provide an additional margin of safety.

In regard to the comments concerning specific mathematical models, as the shape of the dose-response curve is not known, it is not possible to state whether a particular model such as the

linearized multi-stage model underestimates or overestimates the actual risk for a particular chemical. The presentation of upper and lower confidence limits as well as best estimates is a valid means of presenting the results; however such a range of numbers would not help determine the no-effect-level for purposes of determining the RMCL.

7. RMCLs for Carcinogens at a Range of Risk Levels

Comments: Several commenters suggested that RMCLs be set at varying risk levels depending on the strength of evidence of carcinogenicity (see Question 1), however no comments were received which suggested that a range of risk levels instead of a single value be used as the RMCL.

Response: EPA agrees that the RMCL should be a single value, rather than a range of risk levels. A range of risk levels would not serve the purpose of providing a health-based goal with a margin of safety and would be confusing to the public. In addition, RMCLs set at a range of risk levels would not provide a clear target level for setting the MCLs.

8. RMCL and MCL for Total VOCs

Comments: Twenty-six commenters addressed the issue of setting an RMCL and an MCL for total VOCs. Thirteen commenters were in favor of establishing an RMCL for total VOCs while thirteen commenters were against such an RMCL. The major reasons why an RMCL was favored was the need to be protective of public health and consider possible synergistic effects, the suggestion that such an RMCL would make enforcement easier and that an RMCL for total VOCs is supported by the technology (most treatment techniques remove more than one chemical at a time). Many of these commenters also noted that in the absence of more scientific data, EPA should consider the potential health risks of multiple contaminants to be additive. One commenter suggested that a default level of 100 μg/l for total VOCs is reasonable.

The basis for the majority of the comments which did not favor setting an RMCL for total VOCs was that scientific information does not exist to support such a level as it is not possible to state whether compounds will act in an additive, synergistic or antagonistic fashion. One commenter proposed that EPA establish an approach based upon pragmatic considerations, rather than purely scientific considerations. This approach consisted of setting MCLs for individual compounds and then setting a standard in which the total concentration of the mixture should not exceed the MCL of the individual component with the highest MCL. Another commenter felt that an RMCL for total VOCs is not needed because the application of step-by-step safety factors for the individual chemicals tends to build in a bottom line safety factor.

The National Drinking Water Advisory Council recommended that an RMCL for total VOCs not be established at this time due to the lack of scientific data on synergistic, antagonistic or additive effects of exposure to more than one substance at a time. A minority of members of the Council supported establishment of an RMCL for total VOCs in order to protect against the potential additive effects of unregulated VOCs or regulated VOCs present at levels just below their MCLs.

Responses: EPA agrees with the many commenters who believed that an RMCL for total VOCs would not be scientifically valid. EPA is following the recommendations of the National Drinking Water Advisory Council and has concluded that sufficient data are not available upon to which to base an RMCL for total VOCs. There are not adequate data available to indicate that chemicals in mixtures act in an additive fashion; synergistic or antagonistic effects may be seen. EPA agrees with the commenter who stated that, "In summary, VOCs vary greatly in their toxicity and chemical properties. It would not be possible realistically to establish a single RMCL that would represent a no-effect level for the different VOCs that might be found in drinking water".

EPA has provided general guidelines for the assessment of chemical mixtures (50 FR 1170). However, as a matter of priority, EPA is attempting to regulate as many VOCs as possible which meet its criteria for regulation. EPA may reassess additive and synergistic effects at a later date.

In addition, an RMCL for total VOCs would be impossible because both carcinogens and non-carcinogens are regulated. An RMCL of zero adjusted with a higher number would produce a number greater than zero. EPA would not be setting a level that prevented known or anticipated adverse effects for known or probable carcinogens if a non-zero number were chosen. On the other hand, zero as an RMCL for total VOCs would be overly stringent as EPA is today establishing non-zero RMCLs for several VOCs.

B. Additional Issues

1. Analytical Methods

Comments: Two commenters discussed the available analytical methods for monitoring for VOCs in drinkings water. Both of these commenters stated that the EPA methods (550.1, 502.1, 503.1 and 450.1) are not precise, accurate and simple and are more expensive than EPA assumes. The commenters noted that the methods have not been subjected to peer reveiw or evaluated in a scientific manner and interferences are manifold in the analyses.

Responses: For purposes of determining whether a drinking water regulation is appropriate, and therefore in determining whether to set an RMCL, EPA must determine whether contaminants can be detected in drinking water. If there is no way to determine if a contaminant may be in drinking water, EPA is unlikely to establish a drinking water regulation. Therefore, in its RMCL proposal, EPA noted that methods appeared to be available to detect the presence of VOCs in drinking water. Comments relating to the precision, accuracy, cost, and peer review of methods will be addressed in the MCL rulemaking. However, EPA will make a preliminary response to these comments here.

EPA has recently revised two of the methods (502.1 and 503.1) to provide additional information on the precision and accuracy of these methods from an interlaboratory validation study. These methods were tested by 20 laboratories using drinking water spiked with VOCs at various levels. Single operator precision, overall precision and method accuracy were found to be related to the concentration of the analyte.

EPA agrees that interference problems are significant and recommends that precautionary measures to avoid contamination of samples be followed as well as other good laboratory practices in quality control. In reference to costs of analysis, EPA does not believe that EPA's analytical costs are an underestimate of the actual costs per sample. EPA conducted a survey of analytical costs associated with the analysis of VOCs which included 28 commerical laboratories across the United States. The range of prices quoted was from $50 to $300 for Method 502.1 and $75 to $500 for Method 503.1. These prices are presently being charged by these laboratories and appear to be representative of laboratories across the country.

2. Occurrence

Comments: Seven comments were received which addressed the occurrence of VOCs in drinking water. Four commenters noted problems with the EPA surveys used to estimate the occurrence of the VOCs in drinking water. Two of these commenters stated that the surveys have not been made available for outside review and comment and that there were problems with the precision and reproducibility of the data in the surveys. One commenter noted that of the five surveys employed quantitatively to make projections of national occurrence for trichloroethylene, only one was acceptable from both a qualitative and quantitative standpoint. Data from the other four surveys was judged to be only qualitatively acceptable. In addition, this commenter suggested that a major deficiency of several of the surveys was the long unrefrigerated holding period of the samples prior to analysis.

Several commenters provided specific comments on the Occurrence Documents for individual chemicals. The major points discussed dealt with the minimum quantification levels assumed, the additional sources of total exposure (air and food) and the sampling techniques used to estimate national occurrence.

Responses: All of the EPA surveys have been available for outside review and comment before the proposed rule and were included in the rulemaking record available to the public. In addition, the data from these surveys have been summarized and tabulated in the individual occurrence documents on each chemical.

In reference to the occurrence surveys, these surveys are used as general information to support EPA's finding that such contaminants have occurred in drinking water or are likely to occur in drinking water. Their quantitative evidence is not particularly significant in this rulemaking. Therefore, the fact that a contaminant level may have been overestimated or underestimated does not render the studies useless. Projections of national occurrence are provided as background data for determining priorities and for public information and are not used to determine whether or not a compound should be regulated.

In regard to the long holding period of the samples prior to analysis, this holding time can lead to a reduction in the measured contaminant level which is recognized as a potential factor in underestimating the actual occurrence levels. Thus, EPA believes that this holding time does not affect the decision on whether or not to regulate a compound based on occurrence, since the holding period would underestimate the actual occurrence.

EPA has addressed the specific comments on the Occurrence Documents in the background document, "Summary of Comments" and EPA Responses on Federal Register Notices on Volatile Synthetic Organic Chemicals in Drinking Water".

3. Risk Assessment

Comments: Seven commenters discussed varying issues involving the risk assessment process. One commenter stated that EPA has been unable to separate risk assessment from risk management. This commenter felt that EPA regulates a compound because the risk assessment is there, regardless of whether the hazard is real or not. Risk assessment was defined as the summation of all known data on the substance and not merely a statistical exercise.

Another commenter noted that EPA's regulatory objective should be on setting a goal for risk reduction, i.e., maximizing health protection by providing the greatest risk reduction for the population at risk. This commenter felt that this should be accomplished through a process of hazard evaluation in which the data are first examined to determine if they are of sufficient quality to warrant quantitative hazard evaluation. If the data are of sufficient quality, the geometric mean of all the risk estimates should be used. All this information is then made available to the decisionmaker and then the strength of evidence is taken into consideration. The stronger and more reliable the evidence, the less risk one would take, and the weaker the evidence, the higher the estimated risk one may find acceptable.

A commenter stated that EPA should formalize its methodology for risk assessment, seek public comments on the process and ensure that risk assessments are consistent among all Agency programs. One comment was received which suggested that EPA propose alternate approaches for predicting cancer risks for compounds with sufficient and limited evidence of carcinogenicity. This commenter noted that distinctions have not been made between these two classifications with regard to quantitative risk assessment and that the risk assessment process should try to deal in a quantitative manner with differences in the quality of evidence.

One commenter stated that linearized risk assessment models should be abandoned until synergistic data are gathered and another commenter felt that VOC regulations must incorporate a provision allowing the use of water having the lower cancer risk where differing risk estimates exist. An additional comment was received which noted that with federally provided health effects information, the local governments can develop the necessary information to inform the consumers as to the cost in meeting risk. This commenter suggested that the public should be able to vote as to the cost/benefit of meeting the RMCL.

Responses: The process of risk assessment is carried out in several general steps which are dependent upon experienced scientific judgment. Each substance must be evaluated on a case-by-case basis using all of the information at hand, however imperfect it may be. First, the available data is evaluated in order to establish *qualitatively* the potential for adverse health consequences. The general relationship between level of exposure and the nature and severity of effects is evaluated. Next, risk characterization is carried out which involves the quantitation of the risk from an acceptable data base. In the case of the development of drinking water regulations, this step would conclude with the derivation of an RMCL.

The type of data which is used to qualitatively evaluate the potential for adverse health effects include a wide variety of information on toxicity and toxicokinetics obtained in a number of species, even the human, as well as certain types of structure activity relationship investigations. For quantitation of the risk, a more vigorous measure is applied to the acceptability of data. In this case, only studies which are conducted in an appropriate manner (e.g., with sufficient numbers and quality control, etc.) can be included. These studies should identify the presence or absence of a dose-response relationship for at least one if not several parameters in a system which can be extrapolated/interpolated to the human. In addition, at least one of those studies should have adequate duration of exposure (no less than subchronic), preferably but not necessarily by the oral route, and meet the other criteria stated above so that it can be used as the basis for the development of an estimated exposure level on the health of persons with an adequate margin of safety.

EPA agrees that the process of risk assessment should be separated from risk management. EPA first carries out the risk assessment process, as discussed above, and for those chemicals with equivocal evidence of

carcinogenicity and for non-carcinogens, the quantitation of risk is used as the basis for the RMCLs. The risk management process is then carried out which consists of management decisions on how the risk assessment is to be applied. In this case, EPA has adopted the three-category regulatory scheme for contaminants as the risk management decision-making criteria.

EPA does not believe that the RMCLs should be set on the basis of risk reduction, as suggested by one commenter. According to the SDWA, the RMCLs are to be set at levels at which "no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety". Basing the RMCLs upon risk reduction would not allow for an adequate margin of safety and would not be set at the no-effect level, as mandated by the SDWA.

EPA agrees with the comment that the methodology for risk assessment should be formalized. EPA has published Proposed Guidelines for Carcinogen Risk Assessment (49 FR 26294) which is a methodology for assessing carcinogens in a formalized process, including public comment and review. These proposed guidelines discuss a categorization scheme for chemicals based upon strength of evidence of carcinogenicity.

In response to the suggestion that linearized risk models be abandoned, risk extrapolation models which include the linear models are the only methods currently available to estimate cancer risk and EPA believes that they provide a useful function in evaluating relative risks from chemical contaminants. Sufficient scientific data are not available upon which to choose which model is more likely to more reasonably reflect true risks. Of course, these models are not used in establishing RMCLs for carcinogens. They are nevertheless useful in providing a means of incorporating an additional margin of safety for contaminants with equivocal evidence of carcinogenicity.

In response to the suggestion that the local governments develop the necessary information to inform the consumers as to the cost in meeting the risk, EPA feels that the local water utilities should decide with their customers the best means of reducing risk. However, EPA is required under the SDWA to set National Primary Drinking Water Regulations for contaminants that public water supplies must meet.

4. Criteria for Setting RMCLs/MCLs

Comments: Fifteen commenters addressed the criteria to be used to determine the need for regulation of compounds in drinking water. Four commenters suggested that compounds be regulated if they are present in drinking water with some frequency or have widespread occurrence and present a risk to human health. Two commenters noted that data presented by EPA do not reflect a need to regulate many of these compounds, given their minimal incidence of detection in drinking water supplies and the low concentrations at which they are found. One of these commenters felt that controlling these substances will not result in a measurable decrease in cancer incidence.

Six commenters felt that a preventive approach should be used to determine which chemicals should be regulated. These commenters noted that regulation should be considered for contaminants which pose a potential threat to human health if they were to contaminate a public water supply, and that government must err on the side of protection in deciding whether to impose control limits. One of these commenters suggested an approach to regulating compounds for which there are inadequate health data consisting of regulating compounds as a group and setting MCLs for specific chemicals within each group as data become available.

An additional comment was received which stated that EPA should set priorities for the chemicals to be regulated based upon the relative risk levels. A commenter suggested that if substantial doubt exists as to whether a substance causes serious health effects, EPA should provide a regulatory decision which reflects this lack of evidence. Another commenter stated that there is a clear need for national standard setting for VOCs as most States lack the resources to develop standards on their own. This commenter further stated that EPA is the best, and sometimes only, information source in this regard.

The National Drinking Water Advisory Council recommended that the basis for selection of contaminants for regulation should be: (a) Sufficient health effects data, and (b) the occurrence or potential occurrence of contaminants in drinking water. A further condition was recommended that suggested that regulations be set for known human carcinogens, even if they do not occur widely in drinking water. It was recommended that RMCLs be set for all the VOCs in the proposal except for 1,1-dichloroethylene and p-dichlorobenzene, due to the limited occurrence and health effects data on these two compounds. A minority of the members of the Council felt that RMCLs should be set for 1,1-dichloroethylene and p-dichlorobenzene due to health effects information and the potential for widespread occurrence of these compounds in drinking water.

Responses: EPA has used three primary criteria for selection of contaminants for possible regulation: (1) The analytical ability to detect a contaminant in drinking water, (2) the potential health risk and, (3) the occurrence or potential for occurrence in drinking water. These factors are examined for each of the chemicals that EPA is considering regulating, following the "logic train" discussed in section IV. EPA feels that it is appropriate to base the selection of contaminants upon the potential risk and the occurrence or potential for occurrence in drinking water, rather than using widespread occurrence and a significant health risk as the criteria.

Requiring widespread occurrence and a significant risk of harm to the public before regulating would not be consistent with the preventive purpose of the statute. Congress expected EPA to protect public health before adverse effects occurred. The legislative history of the SDWA states, "Because of the essentially preventive purpose of the legislation, the vast number of contaminants which may need to be regulated, and the limited amount of knowledge presently available on the health effects of various contaminants in drinking water, the Committee did not intend to require conclusive proof that any contaminant *will* cause adverse health effects as a condition for regulation of a suspect contaminant. Rather, all that is required is that the Administrator make such a reasoned and plausible judgment that a contaminant *may* have such an effect". Controlling these contaminants when there is some evidence of drinking water contaminantion even if not widespread or at high levels, is clearly consistent with EPA's mandate to protect public health.

In addition, EPA need not determine that there will be a measurable decrease in cancer incidence before it is justified in regulating these drinking water contaminants. First, epidemiological studies on VOCs in drinking water are not available. Second, as noted above, EPA need not wait until a significant harm or risk of harm occurs before regulating drinking water. However, as noted in the draft Regulatory Impact Analysis, EPA believes that the incidence of cancer will be reduced if the proposed MCLs are adopted.

In response to the comment concerning regulation of compounds as

a group, EPA does not agree that compounds should be regulated where there are inadequate health data. The RMCLs are based upon the best available health data and if the data are insufficient as a basis for the derivation of the RMCL, an RMCL will not be set. However, EPA considers it appropriate to regulate compounds as a group as appropriate, as was done in the case of the trihalomethanes.

EPA agrees that priorities of chemicals to be regulated should be set based upon a variety of factors, including relative risk levels. EPA regulates compounds where there is a possibility of an adverse health effect. The RMCLs reflect the degree of evidence of carcinogenicity through the three-category approach, and the lack of evidence is reflected in the chemicals categorized as having "equivocal" evidence of carcinogenicity.

EPA realizes that many States lack resources to develop RMCLs independently. Congress also recognized this fact when it enacted the SDWA giving EPA broad authority to establish standards for drinking water contaminants.

EPA agrees with the minority opinion of the National Drinking Water Advisory Council that there are sufficient health effects information and potential for occurrence in drinking water to set RMCLs for 1,1-dichloroethylene and p-dichlorobenzene. (See the background Summary of Comments document for further discussion of the specific chemicals.)

5. Simultaneous Proposal of RMCLs and MCLs

Comments: Six commenters suggested that the two-step regulatory process be collapsed so that RMCLs and MCLs are proposed simultaneously. Two of these commenters felt that RMCLs and MCLs should be combined into a single set of numbers. The basis was that simultaneous proposal would reduce the potential for confusion by the public and the media, and would reduce the lengthy regulatory process. Two additional comments were received which stated that the current practice of proposing RMCLs prior to MCLs is very confusing. One of these commenters suggested that EPA take special pains to educate the public on the RMCL/MCL process.

Response: EPA agrees that by simultaneously proposing RMCLs and MCLs the regulatory procedure would be shortened and would tend to minimize potential confusion among the public. However, the SDWA currently specifies that RMCLs and MCLs are to be proposed in sequence and EPA will follow this statutory direction.

6. RMCLs as Standards

Comments: Twelve commenters stated that even though RMCLs are intended to be used as non-enforceable guidelines, they will be adapted by States and local agencies as enforceable standards. In addition, it was noted that RMCLs will be applied in areas other than public water systems, such as for hazardous waste clean-up standards and ground water monitoring levels. One of these commenters stated that there is no difference to the populace between a goal and a standard if it is promulgated by EPA.

Responses: RMCLs are only targets for EPA's MCL rulemaking. States may adopt MCLs that are more stringent; however, EPA does not require or encourage States or localities to adopt the RMCLs as enforceable drinking water standards. Any use of RMCLs by EPA or States or localities would have to be accomplished through legislation or rulemaking. The public would have an opportunity to address this or any other use of RMCLs.

7. Control of Contaminants

Comments: Four comments were received that urged EPA to control contaminants at the source and to prevent their discharge into drinking water supplies. One commenter stated that water operators should not be penalized for treating VOCs not naturally found in water.

Responses: EPA agrees that contaminants should be controlled at the source and is working through the National Pollution Discharge Elimination System, the Hazardous Waste and Superfund programs and other EPA programs to control source discharges. The majority of cases of VOC contamination do not involve point discharges to surface water. Most VOC problems are in ground water, where source clean-up is very difficult.

8. Monitoring

Comments: Five commenters addressed monitoring for contaminants in drinking water. Three commenters stated that increased monitoring of drinking water to better define the public's exposure to VOCs is warranted. One comment was received which presented a monitoring scenario in which all public water systems would carry out one round of monitoring for VOCs. If no contamination was detected, the water system would then monitor at three-year intervals. If contamination was detected below the MCLs, monitoring would take place yearly while contamination above the MCL would dictate quarterly samples. This commenter also noted that it is preferable to do preventive monitoring for VOCs than to try afterwards to provide treatment for VOCs removal which is more expensive. An additional commenter was concerned with the reliability of the available monitoring methods and stated that standards should be set in such a manner that recognizes the range of uncertainties that may be inherent in the data generated by the techniques.

Responses: EPA agrees that monitoring is a key element in regulatory compliance as well as in identifying the possible need for additional controls and public information. The uncertainties in the data generated by analytical methods is discussed in the MCL proposal. EPA recognizes that a great deal of variability surrounds the results of the monitoring methods and has factored this uncertainty into the determination of the MCLs. Monitoring is addressed in detail in the MCL proposal.

For the reasons set out in the preamble, Part 141 of Title 40, Code of Federal Regulations is amended as set forth below.

1. The authority citation for Part 141 is revised to read as follows:

Authority: 42 U.S.C. 300g–1, 300g–3, 300j–4, and 300j–9.

2. The title of Part 141 is revised to read as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

3. A new paragraph (u) is added to read as follows:

§ 141.2 Definitions.

* * * * *

(u) "Recommended maximum contaminant level" or "RMCL" means the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which includes an adequate margin of safety. Recommended maximum contaminant levels are nonenforceable health goals.

4. A new Subpart F, consisting of §§ 141.50 and 141.51, is added to read as follows:

Subpart F—Recommended Maximum Contaminant Levels

Sec.

141.50 Recommended maximum contaminant levels for organic contaminants.
141.51 [Reserved]

Subpart F—Recommended Maximum Contaminant Levels

§ 141.50 Recommended maximum contaminant levels for organic contaminants.

(a) RMCLs are zero for the following contaminants:

(1) Benzene
(2) Vinyl chloride
(3) Carbon tetrachloride
(4) 1,2-dichloroethane
(5) Trichloroethylene

(b) RMCLs for the following contaminants are as indicated:

Contaminant	RMCL in mg/l
(1) 1,1-dichloroethylene	0.007
(2) 1,1,1-trichloroethane	0.20
(3) p-dichlorobenzene	0.75

§141.51 [Reserved]

[FR Doc. 85-26415 Filed 11-12-85; 8:45 am]
BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[OW-FRL-2819-4a]

National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rulemaking.

SUMMARY: This action under the Safe Drinking Water Act (42 U.S.C. 300f, *et seq.*) proposes National Drinking Water Regulations and Maximum Contaminant Levels (MCLs) for the following eight volatile synthetic organic chemicals (VOCs) in drinking water: trichloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and p-dichlorobenzene. In addition, monitoring, reporting and public notification requirements for these eight VOCs and 51 other VOCs are proposed.

MCLs are *enforceable standards* and are to be set as close to the Recommended Maximum Contaminant Levels (RMCLs) (health goals) as is feasible and are based upon treatment technologies, costs (affordability) and other feasibility factors, such as availability of analytical methods, treatment technology and costs for achieving various levels of removal.

EPA proposed RMCLs for these eight VOCs and tetrachloroethylene. RMCLs for the eight VOCs are promulgated elsewhere in today's **Federal Register**. New data on the toxicology of tetrachloroethylene has recently become available and the public comment period on the RMCL for tetrachloroethylene has been reopened for 45 days for public consideration of the new data. This action is officially announced elsewhere in today's **Federal Register**. When the RMCL for tetrachloroethylene is promulgated, the MCL will be proposed.

EPA is also proposing best technology generally available for use by public water systems that receive variances under the Act. The proposal specifies criteria by which EPA and States with primary enforcement responsibility shall issue variances and compliance schedules to systems under the Act.

DATES: Written comments should be submitted on or before February 11, 1985. A public hearing will be held in Washington, D.C., on Tuesday, January 13 and 14, 1986, beginning at 9:00 a.m. in Room 3906 Mall, EPA, 401 M St. SW., Washington, D.C.

ADDRESSES: Send written comments on this proposed rule to Comment Clerk, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. Comments are not solicited on the RMCLs. A copy of the comments and supporting documents will be available for review during normal business hours at the EPA, Room 2904 (rear), 401 M Street, SW., Washington, D.C. 20460. Anyone planning to attend the public meeting (especially those who plan to make statements) should register in advance by calling or writing Ms. Arnetta Davis at 202/382-7575, EPA, WH-550, 401 M St., SW., Washington, D.C. 20460. Persons planning to make statements at the meeting are encouraged to submit written copies of their remarks at the time of the hearing.

Supporting documents cited in Section IX will be available for inspection at the Drinking Water Supply Branches in EPA's Regional Offices.

I. JFK Federal Bldg., Boston, MA 02203. Phone: (617) 223-6486, Jerome Healy
II. 26 Federal Plaza, Room 824, New York, NY 10278. Phone: (212) 264-1800, Walter Andrews
III. 6th & Walnut Sts., Philadelphia, PA 19106. Phone: (215) 597-9873, Bernie Sarnoski
IV. 345 Courtland Street, Atlanta, GA 30365. Phone: (404) 881-3781, Robert Jourdan
V. 230 S. Dearborn St., Chicago, IL 60604. Phone: (312) 886-6176, Joseph Harrison
VI. 1201 Elm St., Dallas, TX 75270. Phone: (214) 767-2620, James Graham
VII. 726 Minnesota Ave., Kansas City, KS 66101. Phone: (913) 236-2815, Gerald R. Foree
VIII. 1860 Lincoln St., Denver, CO 80295. Phone: (303) 293-1426, Marc Alston
IX. 215 Fremont St., San Francisco, CA 94105. Phone: (415) 974-8076, Leslie Ragle
X. 1200 Sixth Ave., Seattle, WA 98101. Phone: (206) 442-1225, Jerry Opatz

Copies of the treatment and costs document, the analytical methods/monitoring document, and the analytical methods documents, are available for a fee from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll free number is 800/336-4700; local: 703/487-4650.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, telephone (202) 382-7575.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Statutory Requirements and Regulatory Framework
II. Background: RMCLs for VOCs
III. Proposed MCLs and Best Technology Generally Available
A. MCL vs. Treatment Technique Regulation
B. Analytical Methods
1. Availability of Methods
a. Precision and Accuracy
b. Specificity
c. Laboratory Availability
d. Repidity
e. Costs
2. Method Detection Limits and Practical Quantitation Levels
3. Laboratory Performance Requirements
4. Request for Comments on Analytical Methods
C. Technologies and Costs
1. Aeration
a. Performance Potential of Aeration
b. Feasibility/Reliability of Attaining Specific Levels
c. Secondary Effects of Aeration
d. Cost of Packed Tower Aeration
2. Adsorption (Granular Activated Carbon)
a. Performance Potential/Feasibility of GAC
b. Secondary Effects of GAC Adsorption
c. Cost of Controlling VOCs using GAC
3. Other technologies
4. Best Technology Generally Available
a. BTGA: Packed Tower Aeration: GAC
b. Other technologies: ultra-violet—ozone oxidation
c. Other technologies: reverse osmosis
d. Other technologies: non-treatment alternatives
e. Other technologies: point-of-use/point-of-entry treatment devices
5. Bottled Water
D. Selection of MCLs
1. Analytical Methods
2. Availability/Performance of Treatment Technologies
3. Levels of VOC Occurrence
4. Other Technical Feasibility Factors
5. Costs of Treatment
E. Proposed MCLs
F. Applicability to Certain Non-community Water Systems
IV. Best Technology Generally Available for § 1415 Variances
V. Compliance Monitoring Requirements
A. Proposed Monitoring Requirements
1. Option 1
2. Option 2
3. Option 3
4. Selection of Monitoring Requirements
B. Determination of Compliance with MCLs
C. Public Comments
VI. Monitoring for Unregulated Contaminants
A. Summary Statement of the Problem
B. Statutory Authority
C. Background
D. Summary of Proposal
1. Selection of Contaminants

2. Proposed Monitoring Requirements for Unregulated VOCs
a. Option 1
b. Option 2
c. Option 3
d. Selection of Monitoring Requirements
VII. Reporting Requirements
VIII. Public Notice Requirements
IX. Economic Impact Assessment
A. Alternatives Examined
B. Economic Impacts
C. Benefits
D. Uncertainty
E. Major Rules
F. Regulatory Flexibility Analysis
G. Paperwork Analysis
X. Public Docket/References
XI. Request for Public Comment

I. Statutory Requirements and Regulatory Framework

The Safe Drinking Water Act (42 U.S.C. 300f, *et seq.*) ("SDWA" or "the Act") requires the EPA to establish primary drinking water regulations which (1) apply to public water systems; (2) specify contaminants which in the judgment of the Administrator, may have any adverse effect on the health of persons; (3) specify for each contaminant either (a) maximum contaminant levels (MCLs) or (b) treatment techniques. See Section 1401(1), 42 U.S.C. 300f. A treatment technique requirement would only be set if "it is not economically or technologically feasible" to ascertain the level of a contaminant in drinking water.

The SDWA includes provisions for interim and revised primary drinking water regulations. See Section 1412, 42 U.S.C. 300g–1. Interim regulations were to be established within 180 days of enactment of the SDWA. Revised regulations are to be developed in two steps: the Agency is to establish RMCLs and then establish MCLs as close to the RMCLs as feasible. MCLs are to be proposed at the time of promulgation of the RMCLs.

RMCLs are non-enforceable health goals. RMCLs are to be set at a level which, in the Administrator's judgment, "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". Section 1412(b)(1)(B).

MCLs are the enforceable standards. MCLs must be set as close to RMCLs as is feasible. Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)." Section 1412(b)(3). The legislative history suggests that MCLs should be based upon performance of technologies affordable by large systems and relatively clean intake waters. H.R. 93–1185, 93rd Cong. 2d Sess. at 4–5 (1974).

Variances and exemptions are available for systems, including small systems, that cannot meet the MCL due to their raw water quality or compelling factors, including economic factors. Sections 1415 and 1416.

Primary drinking water regulations under the Act are to include monitoring requirements. Section 1401(1)(D). Specifically, primary regulations are to contain "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including quality control and testing procedures to insure compliance with such levels * * *". In addition, section 1445 states, "every person who is a supplier of water * * * shall establish and maintain such records, make such reports, conduct such monitoring and provide such information as the Administrator may reasonably require by regulation to assist him in establishing regulations, * * * in evaluating the health risks of unregulated contaminants or in advising the public of such risks".

The SDWA provides that if a State determines that, because of raw water sources, a system cannot meet an MCL despite installation and/or use of the "best technology, treatment techniques, or other means which the Administrator finds to be generally available," taking costs into consideration, it may grant a variance to the MCL. Section 1415(a)(A), 42 U.S.C. 300g–4(a)(1)(A). A variance, if granted, would insulate the system not in compliance from enforcement actions for exceeding an MCL. The system, however, would be required to install and/or use the best generally available treatment methods identified that are available and effective for that system in reducing levels of VOCs. In addition, pursuant to section 1414(c)(2), 42 U.S.C. 300g–3(c)(2), any system that receives a variance, must give public notice of such variance to the persons served by it.

Exemptions, under section 1416, are available to systems (including small systems) who are unable to comply with the MCLs due to compelling factors which may include economic factors. To be eligible, a system must have been in operation on the effective date of the MCL or if not, only if no reasonable alternative source of drinking water is available. The granting of the exemption must not result in an unreasonable risk to health. Unlike a variance, a system need not install and/or use the best treatment generally available as a condition of receiving a variance.

Public notification requirements (section 1414(c)) require that any violation of a maximum contaminant level, failure to comply with an applicable testing or monitoring provision, and the failure to comply with the requirements of a variance or exemption be reported to the persons served by the water system.

States may assume primary enforcement responsibility (primacy) for public water systems under SDWA § 1413. To assure primacy, States must adopt drinking water regulations that are no less stringent than EPA's National Primary Drinking Water Regulations and other supporting authority. *See* SDWA section 1413(a). States which grant variances must also issue such variances in a manner no less stringent than EPA's issuance of variances. States must, therefore, adopt EPA's primary MCLs and associated monitoring requirements but need not adopt the RMCLs, or variances to assume or retain primacy.

II. Background: RMCLs for VOCs

RMCLs were promulgated for the following eight VOCs in drinking water: trichloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene and p-dichlorobenzene. For background on the RMCLs and information/data on the occurrence of these VOCs in drinking water and potential health effects of human exposure, see the preamble to the final rule on RMCLs and supporting documents listed in that notice and published elsewhere in today's Federal Register. RMCLs for substances considered to be probable human carcinogens were set at zero and RMCLs for substances not treated as probable human carcinogens were set based upon chronic toxicity or other data. Table 1 summarizes the final RMCLs for the VOCs.

An RMCL was proposed for tetrachloroethylene at zero at the same time as RMCLs were proposed for the above eight VOCs. New toxicological data has recently become available and thus the public comment period has been reopened for public consideration. The RMCL will be promulgated after consideration of the public comments; the MCL for tetrachloroethylene will be proposed at that time. Information and data on analytical methods, treatment technologies and costs are presented in this preamble on tetrachloroethylene along with the other VOCs. However, an MCL for tetrachloroethylene is not proposed today.

TABLE 1.—FINAL RMCLS FOR THE VOCS

Compund [1]	RMCL
Benzene	Zero.
Vinyl chloride	Zero.
Carbon tetrachloride	Zero.
1,2-Dichloroethane	Zero.
Trichloroethylene	Zero.
1,1-Dichloroethylene	0.007 mg/l.
1,1,1-Trichloroethane	0.20 mg/l.
p-Dichlorobenzene	0.75 mg/l/.

[1] The RMCL for tetrachloroethylene was proposed at zero. New toxicological data appear to confirm that zero is appropriate but the public comment period is reopened today for public comment on the new data.

III. Proposed MCLs and Best Technology Generally Available

MCLs are to be set "as close to" the RMCLs "as is feasible". The term "feasible" means "feasible with the use of the best technology, treatment techniques, and other means, which the Administrator finds are generally available (taking costs into consideration)". Section 1412(b)(3).

The general approach to setting MCLs is to determine feasibility of controlling contaminants. This requires an evaluation of: (1) The availability and cost of analytical methods, (2) the availability and performance of technologies and other factors relative to feasibility and identifying those that are "best" and, (3) an assessment of the costs of the application of technologies to achieve various concentrations. Key factors in the analyses include the following:

- Technical and economic availability of analytical methods: precision/accuracy of analytical methods that would be acceptable for accurate determination of compliance, limits of analytical detection, laboratory capabilities, and costs of analytical techniques.
- Concentrations attainable by application of best generally available treatment technologies.

—Levels of VOC contamination in drinking water supplies.
—Feasibility/reliability of removing VOCs to specific concentrations.

- Other feasibility factors relating to the "best" means of treatment such as air pollution and waste disposal and effects on other drinking water quality parameters.
- Costs of treatment to achieve contaminant removal.

Proposed MCLs for the eight VOCs are presented in Table 2; the MCLs were determined based upon the following key factors:

- Best technologies generally available are packed tower aeration and granular activated carbon (GAC) adsorption.
- Raw water VOC removal of 90 to 99 percent (and 90–99.9% for vinyl chloride) is a reasonable expectation of performance by packed tower aeration and GAC adsorption.
- The Practical Quantitation Level (PQL) for the VOCs is 5 μg/l except for vinyl chloride which has a PQL of 1 μg/l. The PQL is defined as the lowest achievable level of analytical quantitation during routine laboratory operating conditions within specified limits of precision and accuracy.

Provided below are summaries of the availability of analytical methods, treatment technology performance and costs, and the rationale used to determine the proposed MCLs. A more complete explanation is found in the Cost and Technologies document and the Analytical Methods/Monitoring document listed in the end of this notice.

TABLE 2.—PROPOSED MCLS

Compound [1]	MCL mg/l
Trichloroethylene	0.005
Carbon tetrachloride	0.005
Vinyl chloride	0.001
1, 2-Dichloroethane	0.005
Benzene	0.005
1,1-Dichloroethylene	0.007
1,1,1-Trichloroethane	0.20
p-Dichlorobenzene	0.75

[1] The MCL for tetrachloroethylene will be proposed later—see text, Section II—Background.

A. MCL vs. Treatment Technique Regulation

The SDWA specifies in section 1401 that an MCL is to be set for contaminants in drinking water if "it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems." If it is not, a treatment technique regulation is to be set.

For the purposes of making the finding regarding the feasibility of monitoring for any given contaminant, EPA must first determine, with respect to a given contaminant, what effective analytical techniques, if any, are technologically available. Next EPA must determine at what frequencies those techniques should be employed to assure detection of any violation prior to the time the violation will actually cause or contribute to any significantly increased health hazard. Then EPA must determine whether monitoring at that frequency is economically feasible. H.R. 93–1185, 93rd Cong. 2d Sess. at 11–12 (1974).

In this proposal, three analytical techniques have been identified and are clearly technologically available. As discussed in Section IV, EPA is proposing to require monitoring quarterly where VOCs are detected. This monitoring frequency will detect violations of the MCL before there is any significantly increased health hazard, as VOCs present only potential long-term risks at the concentrations normally found in drinking water. Quarterly reporting is also proposed to account for the data which suggest that VOC raw water concentrations may vary under some circumstances. At $150 to $200 per sample, quarterly monitoring is economically feasible for public water systems. For example, monitoring costs for a system serving 100 people with two wells would be a total of $1 per month per person for one year. For a system of 25 people with one well, costs would be $2 per month per person for one year. Costs for larger systems would be much less. Monitoring on a daily or weekly basis might not be economically feasible in all cases. Monthly monitoring might be economically feasible for larger communities but would not generally be necessary to detect significantly increased health hazards given the long-term risks from VOCs.

Although VOCs can sometimes be reduced below the practical quantitation level using best generally available technology (BGAT), EPA does not believe a treatment technique should be required instead of an MCL. First, Congress requires EPA to set a treatment technique instead of an MCL when monitoring is not economically and technologically feasible. EPA believes that Congress intended EPA to require use of treatment techniques whenever a method was substantially infeasible across a broad range of contamination levels. In this case, monitoring is economically and technologically feasible across a very broad range of contamination levels.

Second, if a treatment technique were proposed for the VOCs, it would have to be based on a treatment performance measurement parameter which is more sensitive than the analytical test methods for VOCs. There is no known parameter and its development is not foreseeable in the near future. Similarly, if EPA were to prescribe a treatment technique for VOCs, there would still remain the question of whether an individual system would have to implement the prescribed technique. EPA can only identify those systems that need the treatment technique by having the systems monitor for the VOCs. Obviously, monitoring data are only valid above the verifiable level of quantitation, and only those systems with VOC contamination at or above the verifiable level would have to install the technique. Therefore, setting the MCL at the limit of quantitation provides

essentially the same level of protection as a treatment technique and provides the added advantage of allowing compliance monitoring. Standard design and operating procedures would result in treated water concentrations somewhat below the MCL. This allows a margin of safety during periods of changing water quality, ambient temperature conditions or other unanticipated conditions.

EPA requests comment on whether a treatment technique or an MCL should be set for these VOCs.

B. Analytical Methods

The analytical methods used for compliance monitoring must be "economically and technologically feasible to ascertain the level of such contaminant in water in public water systems" (SDWA, section 1401(1)(C)).

The reliability of analytical methods used for compliance monitoring is critical at the maximum contaminant level. Therefore, the analytical methods have been evaluated with respect to the accuracy or recovery (lack of bias) and precision (good reproducibility) at the range of MCLs being considered for all nine VOCs. The primary purposes of these evaluations is to determine:

- Whether analytical methods are technically available to measure VOCs in drinking water, and
- What are reasonable expectations of technical performance by analytical laboratories at levels considered for MCLs.
- What are the costs of analysis for VOCs.

1. Availability of Methods

Numerous analytical techniques have been developed for the determination of volatile chemicals in drinking water. The selection of analytical methods for compliance with these regulations includes consideration of the following factors:

(a) Reliability (i.e., precision/accuracy) of the analytical results,

(b) Specificity in the presence of interferences,

(c) Availability of enough equipment and trained personnel to implement a national monitoring program (i.e., laboratory availability),

(d) Rapidity of analysis to permit routine use, and

(e) Cost of analysis to water supply systems.

These methods involve the use of gas chromatography (GC) with either conventional detectors or a mass spectrometer (GC/MS).

The EPA has developed three analytical methods based on these techniques that is has determined are "economically and technologically feasible" for compliance with one or more of the proposed MCLs. The methods are specified below.

1. Method 502.1, "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography".

2. Method 503.1, "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography".

3. Method 524.1, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry". These analytical methods use the purge and trap technique for the extraction of volatile constituents from the aqueous phase and concentration in a column containing a sorbent. The compounds are thermally desorbed from the column and backflushed onto the head of a GC column. This is followed by separation of constituents in the GC column and measurement with a specific detection system.

a. *Precision and Accuracy.* Method 502.1 recommends the use of a column containing 1 percent SP-1000 on Carbopack-B for the separation of contituents that are detected with a halide specific detector (HSD). An electrolytic conductivity detector (EICD) or a microcoulometric detector are recommended for this purpose. This method may be used for the determination of eight VOCs (it does not measure benzene). The single laboratory accuracy and precision have been determined by analysis of replicate samples of finished drinking water and raw source water spiked at levels of 0.2 or 0.4 μg/l for these compounds. The results show an accuracy, expressed as percent average recoveries, ranging from 88 to 110 percent, and a precision, expressed as percent relative standard deviations, ranging from 6 to 15 percent for the eight VOCs.

Method 503.1 recommends the use of a column containing 5 percent SP-1200+1.75% Bentone 34 on Supelcoport for the separation of constituents that are then detected with a photoionization detector (PID). This method may be used for the determination of benzene p-dichlorobenzene, vinyl chloride, 1,1-dichloroethylene, trichloroethylene, and tetrachloroethylene. The single laboratory accuracy and precision have been determined by analysis of replicates of finished drinking water and raw source water spiked at levels of 0.40 and 0.5 μg/l for benzene and p-dichlorobenzene, respectively. The results show an average percent recovery of 100 percent and a relative standard deviation of 2.8 percent for benzene and an average percent recovery of 95 percent and a relative standard deviation of 6.4 percent for p-dichlorbenzene.

Method 524.1 recommends the use of a column containing one percent SP-1000 on Carbopack B for the separation of constituents, which are detected with a mass spectrometer. VOCs are identified by comparing their mass spectra to the spectra of standards analyzed under identical conditions. All nine VOCs may be determined using this method. The single laboratory accuracy and precision have been determined for the nine VOCs by analysis of seven aliquots of reagent water spiked at levels of 1 or 5 μg/l. The results show average recoveries ranging from 88 to 109 percent, and relative standard deviations ranging from 3.6 to 13.6.

The precision and accuracy results summarized above for Methods 502.1, 503.1 and 524.1 are from a highly experienced single laboratory and they would not be expected to be achieved in routine practice in typical laboratories.

EPA has conducted single-laboratory evaluations for Methods 502.1, 503.1 and 524.1. The objective of these evaluations was to determine the precision and accuracy of the method under practical and routine laboratory conditions. Some multi-laboratory data have been collected from PE studies conducted by EPA, and EPA believes that sufficient data are available from these studies that demonstrate that the methods are available for use in monitoring for VOCs. Public comments are requested on the availiability of these methods for VOC monitoring and if these methods are sufficiently validated to be used for compliance monitoring.

b. *Specificity.* The analytical methods selected for compliance must be specific in the presence of interferences. That is, the method must specifically and correctly identify the contaminant of concern and not confuse it with another chemical. Separations by gas chromatography techniques are not always complete, particularly in complex (multi-contaminant) mixtures. Several compounds within a mixture which have similar chemical and/or physical properties may coelute from the column along with the compounds of interest. Conventional gas chromatography detectors are not always able to discriminate between the compounds of interest and the interfering compounds. The proposed GC methods recommend that when conventional detectors are used, a second column containing a different stationary phase should be used, to provide additional assurance that the

qualitative identifications are indeed the compounds of interest. However, since some VOCs are amenable to both photoionization and halogen specific detectors, the second detector may provide the same degree of confirmation as a second column analysis.

A mass spectrometer usually is able to discriminate between the compounds of interest and interfering compounds. Thus, it is the preferred detection system to provide unequivocal identification in such cases.

c. *Laboratory Availability.* There are approximately 60 laboratories which participate regularly in EPA's Water Pollution performance evaluation studies for VOCs. In addition, there are approximately 200 laboratories which participate regularly in EPA's Water Supply performance evaluation studies for trihalomethanes (THMs). The principles of sample collection and analysis for VOCs are similar to those used for the determination of the four regulated THMs except that the THM MCL (0.10 mg/l) is about 2 orders of magnitude higher than the limits being proposed for the VOCs. The selected procedures use equipment and skills available in many drinking water laboratories. Therefore, EPA feels that there are analytical laboratories available with the expertise required to conduct VOC analysis on a routine basis.

Vinyl chloride, however, presents special analytical problems in the analysis, especially at concentrations near 1 μg/l. Reliable preparation and analysis of samples for vinyl chloride is expected only from the most experienced laboratories. Thus, few laboratories are available to measure vinyl chloride at concentrations near 1 μg/l routinely. Since the proposed monitoring regime (see Section V) would require fewer analyses for vinyl chloride on the most experienced laboratories would be expected to be used for vinyl chloride analysis.

d. *Rapidity.* Estimated analysis time including sample preparation and quality assurance is about one hour per sample. This is comparable to the analysis time required for THM analysis. The selected methods are sufficiently rapid to permit routine use in the examination of a large number of samples.

e. *Costs.* EPA conducted an assessment of analytical costs associated with the analysis of VOCs in drinking water. This assessment included 28 commercial laboratories chosen from those participating in EPA's performance evaluation sample program and which are performing VOC analyses by methods consistent with the proposed methods. The cost comparison below summarized the findings.

COST COMPARISON OF VOC ANALYSES

	GC/MS	GC[1]
Average cost	$197	$187
Range	50-300	75-500
Number of laboratories	23	13

[1] Includes both halocarbons and aromatics by HSD and PID, separately.

The average quote for the sum of separate VOC analyses using GC with halogen-specific and photoionization detection for halocarbons and aromatics, respectively, was $187 per sample and ranged from $75 to $500 per sample. The average cost of VOC analysis using GC/MS was $197 per sample, and ranged from $50 to $300 per sample. The range in prices quoted by the laboratories may be due to differences in the number of samples analyzed routinely by these laboratories and the amount of quality assurance associated with the analyses. These costs were quoted for analysis for all VOCs listed in the methods or about 60 VOCs. When asked for quotes for just 10 VOCs, the laboratories generally stated it would be the same quote; 2 of the 13 GC laboratories quoted $28 per sample less and 3 of the 23 GC/MS laboratories quoted $50 per sample less. These quotes took into account that analysis of all nine VOCs may require two analyses depending upon the equipment in a particular laboratory. In addition, a confirmatory secondary column analysis might be needed for some VOCs in cases where GC/MS is not used.

The analysis of VOCs using the photoionization and electrolytic conductivity detectors in series has been reported by some laboratories. Methods 502.1 and 503.1 include use of detectors in series as an alternate. Simultaneous analysis of violatile halocarbons and aromatic hydrocarbons most likely will result in lower analytical costs (total cost estimated at about $150 per sample). EPA expects that many analytical laboratories will opt to use detectors in series or GC/MS, and that the analytical costs will thereby be reduced.

2. Method Detection Limits and Practical Quantitation Levels

In general, EPA defines the method detection limit (MDL) as the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the true value is greater than zero. The specification of such a concentration is limited by the fact that MDLs are a variable affected by the performance of a given measurement system. MDLs are not necessarily reproducible over time in a given laboratory, even when the same analytical procedures, instrumentation and sample matrix are used.

The lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions is the Practical Quantitation Level (PQL). The PQL thus represents the lowest level achievable by good laboratories within specified limits during routine laboratory operating conditions. The PQL is determined through inter-laboratory studies, such as the PE studies. Differences between MDLs and PQLs are expected since the MDL represents the lowest achievable level under ideal laboratory conditions whereas the PQL represents the lowest achievable level under practical and routine laboratory conditions.

If data are unavailable from inter-laboratory studies, PQLs are estimated based upon the MDL and an estimate of a higher level which would represent a practical and routinely achievable level with relatively good certainty that the reported value is reliable. Traditionally, this level has been estimated at 5 to 10 times the MDL. EPA believes that setting the PQLs in a range between 5 and 10 times the MDL achieved by the best laboratories is a fair expectation for most State and commercial laboratories. Public comment are specifically requested on the expectation that 5 to 10 times the MDL is a good general rule as to what levels can be expected to be measured by commercial laboratories with reliability.

A recent survey of seven U.S. EPA laboratories and contract laboratories serving the EPA reported MDLs averaging from 0.2 to 0.5 μg/l for the nine VOCs in this proposed regulation. The approximate MDLs of 0.2 to 0.5 μg/l are the result of measurement made by a few of the most experienced laboratories under non-routine and very controlled conditions. These levels are not expected to be representative of the capabilities of a cross-section of good laboratories performing compliance VOC measurements on a routine basis.

The PQLs for the VOCs have been determined based primarily upon the results of performance data from EPA and non-EPA sources, multi-laboratory method validation studies and performance evaluation studies. Table 3 provides a summary of recent WP performance evaluation studies by EPA and State laboratories (WP studies #8-11). This table summarizes the result if the limits of precision and accuracy were set at ±20% and ±40% of the reference "true" value for VOC

603-673-8105.

concentrations of 20 μg/l and below. These result are considered to be optimum since they were drawn from experienced laboratories operating under conditions where they knew they were being tested with standard samples in distilled water and without matrix interferences. Actual day to day operations in a wide variety of laboratories using "real" samples in natural water would be expected to produce poorer results, i.e., wider performance ranges especially at the lower concentration levels. Similar multi-laboratory data are not available for 1,1-dichloroethylene and vinyl chloride.

TABLE 3.—PERFORMANCE EVALUATION STUDIES

	TV (μg/l)	No. of labs	No. of labs outside ±20% TV	No. of labs outside ±40% TV
Benzene	7.10	31	12	6
	9.4	32	5	2
	14.1	28	5	1
	18.8	28	8	4
Carbon tetrachloride	6.02	31	10	5
	10.5	35	6	2
	12.0	40	12	3
	16.9	37	7	2
1,2-dichloroethane	6.43	35	11	3
	15.9	29	5	3
	17.1	34	3	0
	19.1	38	7	3
Trichloroethylene	4.99	30	6	3
	8.32	38	8	2
	12.0	36	8	2
	16.8	35	5	2
Tetrachloroethylene	6.08	38	11	5
	11.0	36	4	1
	12.2	30	6	4
1,1,1-trichloroethane	1.61	39	16	9
	6.42	31	6	3
	7.96	35	8	2
	15.9	35	6	0
p-Dichlorobenzene	5.5	18	5	2
	11.0	18	5	4
	13.7	14	8	1

TV = "true" value or reference concentration.

The available data demonstrate that the number of laboratories producing unacceptable data generally increases as the concentration decreases. In the 5 to 20 μg/l range, the failures rates appear among the better laboratories under known test conditions to fall between 10 and 30% (some exceptions) using the ±20% of the true value acceptance limit. From 0 to 20 percent of the laboratories fail to meet the ±40% of the true value acceptance limit at concentrations of 5 to 20 μg/l. It is emphasized that these are EPA and States laboratories, many of which are certified for THM analysis and have extensive experience, proper laboratory instruments, and trained analytical chemists. Illustrating the difficulty of attaining accuracy by laboratories using these methods, after four years of experience analyzing THMs, 15% of those laboratories still fall outside the acceptance limits using ±20% at 0.10 μg/l (100 μg/l) for THMs. While specific data are unavailable at this time, the percentage of private commercial laboratories expected to be able to meet specified performance limits when compared to EPA and State laboratories will likely be lower.

The data in Table 3 suggest that 5 μg/l would be achievable by most laboratories within ±40%. A value of ±40% was determined to be appropriate based upon the desire to set the smallest interval on precision and accuracy (i.e., ± some percentage) that could be achieved by most good laboratories (e.g., 80–100%). Thus, a limit of ±20% would have been more desirable than ±40% but the data in Table 3 showed that fewer laboratories would be able to achieve that level. The PQLs are therefore being proposed at 5 μg/l for the VOCs in Table 3. While data at levels less than 5 μg/l are limited, use of the general rule of "5 to 10 times the MDL" for estimating feasible detection limits for commercial laboratories shows that a PQL of 5 μg/l is reasonable for these compounds. The PQL for 1, 1-dichloroethylene is based upon its similarity in analysis (e.g., same analytical method, similar chemical structures and similar GC retention times) to the VOCs in Table 3 and is also reasonable to be set at 5 μg/l.

Vinyl chloride poses a greater analytical challenge than for the other VOCs because it is gaseous at ambient conditions.

In view of the analytical difficulties and the observation that vinyl chloride consistently occurs in ground waters in the presence of other halogenated two-carbon VOCs, monitoring for vinyl chloride will only be required for ground water systems when the systems detect other VOCs (see discussion below in *Compliance Monitoring Requirements).* EPA believes that is reasonable to use a more conservative approach in setting the PQL for vinyl chloride than described for the other eight VOCs for several reasons. There are: (1) A much smaller number of systems would be required to monitor for vinly chloride as opposed to other VOCs in this proposal, (2) vinyl chloride analysis will be carried out on a sample which has already been characterized for a number of related VOC compounds, which would in effect improve a laboratory's measurement efficency, and (3) vinly choloride analysis requires special handling resulting in what can be more focused attention and careful analysis procedures. Because multilaboratory performance data are unavailable at this time at relatively low concentrations (i.e., 1–5 μg/l), the determination of the proposed PQL for vinyl chloride has been made by taking the low end of the MDL range given earlier (0.2 μg/l) and multiplying by a factor of 5. These choices reflect the fewer and more focused expert analyses required of this chemical.

3. Laboratory Performance Requirements

The question of reasonable expectations of performance by analytical laboratories for the determination of VOCs at or around the proposed MCLs suggests that EPA should establish performance requirements for laboratories analyzing compliance samples for VOCs.

EPA recognizes that the effectiveness of the proposed regulations is dependent upon the ability of analytical laboratories to produce reliable data at relatively low levels for these contaminants. It is important to apply the concepts of quality assurance (QA) to all aspects of data gathering activities, i.e., collection, transport and storage of samples, analytical procedrues, and manipulation and storage of data. The existing drinking water laboratory certification program (LCP) provides guidance for the establishment of minimum QA and quality control (QC) criteria for those analytical laboratories conducting compliance monitoring measurements. Today EPA is proposing criteria of ±40% at concentrations less than 10 μg/l and ±20% above 100 μg/l as mandatory requirements. Additional criteria will be developed later.

The LCP has established the use of external checks of performance to evaluate the ability of laboratories to analyze samples for specific contaminants and to produce data within specific limits. For this purpose, EPA provides performance evaluation (PE) samples to laboratories on a regular basis; participation in this program is a prerequisite for a laboratory to achieve certification and to remain certified for analyzing compliance samples (EPA's laboratory certification program is not mandatory). Achieving acceptable performance in these studies of known test samples provides some indication that the laboratory is following proper practices, and assures that the same practices are also followed under routine conditions. Unacceptable performance may be indicative of problems that could impact on the reliablility of all data generated for specific contaminants. Unacceptable performance should trigger an investigation to establish the possible

cause(s) and to take corrective action. EPA recognizes that even a superior analytical laboratory would occasionally produce data that are outside the acceptable limits for statistical reasons rather than any actual analytical problems. A provision for follow-up analysis is necessary if a laboratory fails the inital determination to decrease the likelihood of statistical error and to determine if a real problem exists.

In the present program, the Quality Assurance Branch of EPA's Environmental Monitoring and Support Laboratory in Cincinnati (EMSL–CI) sends laboratories a set of stable sample concentrates in sealed glass ampules with instructions for dilution of the samples with reagent water and a report form to report the analytical results. The Quality Assurance Branch determines if the concentrations reported are within certain acceptance limits and a detailed analysis of the reported analytical results is returned to the laboratories. Annual participation and acceptable performance in these studies is mandatory for retaining certification. Two studies are conducted every year; the second study is intended as a follow-up for those laboratories failing the primary study.

Acceptable laboratory performance in analyzing drinking water samples have historically been set by EPA using two different approaches; regressions from performance of pre-selected laboratories or specified accuracy requirements. EPA is evaluating these two and other approaches in the development of laboratory performance requirements for the VOCs.

The approach used for contaminants included in the Interim Regulations (except for trihalomethanes) has been to determine acceptance limits from regressions analyses on historical data (Britton and Lewis, 1984). Data obtained under known testing conditions (PE studies) from the most capable of participating laboratories are used (after outlier testing to exclude extreme data points) to derive regression equations, i.e., linear relationships between a reference "true" concentration and the mean reported value and between the reference concentration and the standard deviation. These linear relationships developed from a select group of highly experienced laboratories are then used to determine acceptance limits for all participating laboratories based upon a 95 percent confidence level. In other words, a good laboratory is expected to produce data within the acceptable limits approximately 95 percent of the time. For these VOCs, approximately 90 percent of laboratories would be expected to be within ±40% of the true value for concentrations less than 10 μg/l and within ±20% for levels above 100 μg/l. These are the proposed performance criteria for VOCs.

If historical statistics are not available, acceptance limits are set from the data generated from current PE studies. Acceptance limits based on study statistics result in limits which vary with time and depend on the overall performance of the pre-selected participating laboratories. Thus, these limits could vary with time in either direction as a function of the performance of a given group of laboratories in a particular study. The resulting acceptance limits take into consideration that the accuracy and precision of the measurement are usually related to the concentration of the analyte, i.e., the acceptance range is wider at lower concentration levels since the expected performance is generally poorer at low concentrations. This approach also considers any bias inherent in the analytical procedure used since the acceptance limits are set around the mean reported value and not around the reference "true" value. They would also reflect variability in the performance of the participating laboratories.

The other approach has been applied to the trihalomethanes where the acceptance limits were set at ±20% of the reference "true" value in the range of 0.10 μg/l. This second approach requires that each laboratory demonstrate its ability to perform within certain pre-defined limits. Laboratory performance is evaluated using a constant yardstick independent of the performance achieved by other laboratories participating in the same PE study. A fixed criterion based on a percent error around the "true" value reflects the experience obtained from numerous laboratories and includes relationships of the accuracy and precision of the measurement to the concentration of the analyte and it assumes little or no bias in the analytical methods that may result in average reporting values different from the reference "true" value. This concept assures that reported results can be related to a percentage of variance from the MCL. Precision and bias are considered in setting the MDL, PQL and MCL, and no further introduction of variance due to highly variable performance is acceptable. This approach (setting a ±40% and ±20% limit) would be used to certify laboratories under the LCP to perform analyses that would be required by this proposed rule.

EPA has also considered the use of other alternative approaches to setting acceptable limits for laboratory performance. One such approach is the use of a percentage around the mean reported value instead of the reference value. This approach could be used to account for bias in the analytical procedure.

EPA has previously used the following performance criteria with contractor laboratories for the VOCs:

- The reported value must be within ±20% of the reference value for concentrations of 100 μg/l or above, and
- The reported value must be within ±40% of the reference value for concentrations below 10 μg/l. Table 3 summarized available data using these criteria.

EPA proposes to use the "plus or minus percent of true value" approach (i.e., ±40%, ±20%) in setting MCLs and in certifying laboratories conducting compliance analyses for the VOCs. These performance criteria would be applicable at concentrations at or near the MCL.

- EPA is continuing to conduct additional data-gathering activities for the VOCs, particularly at levels below 10 μg/l. One such effort involves the inclusion of PE samples for the VOCs to an upcoming water supply performance evaluation study scheduled for the fall of 1985.

4. Request for Public Comments on Analytical Methods

Public comment and information on all aspects of the issues presented in this section are requested to assist EPA in making a final choice of monitoring methods and the specific performance requirements in the final rule. Supporting data/information is requested for any comments provided. Specifically, public comment is requested on the following questions.

- Are the proposed analytical methods technically and economically available?
- What is the precision/accuracy of the analytical methods at the proposed MCL levels? Can lower levels of VOCs be measured with reasonable accuracy and precision? Are other precision and accuracy data available on these methods?
- Are the estimated analysis costs accurate and reasonable?
- Are there sufficient qualified laboratories capable of monitoring at concentrations such as the proposed MCLs?

• Is EPA's selection of a plus or minus percent range of true value approach reasonable?

• What specific acceptance limits should be set for laboratory performance in the LCP? Are the following performance criteria which EPA has previously used for its contract laboratories reasonable (i.e., ±20% of the expected value for concentrations at or above 100 μg/l and ±40% of the value for concentrations below that level)? How many laboratories would be able to meet these performance criteria?

• Is the MDL–PQL concept reasonable and acceptable? Is a PQL at 5–10 times the MDL a reasonable expectation for most State and commercial laboratories? Must EPA have single laboratory data or multi-laboratory validation data on precision and accuracy at low levels before it can establish PQLs?

• Are PQLs of 5 μg/l for eight VOCs and a PQL of 1 μg/l for vinyl chloride reasonable? Should the PQL for vinyl chloride be set at a higher level?

• Have the methods been sufficiently demonstrated to be reliable and accurate to be available for VOC monitoring? Is the EPA plan to complete formal method multi-laboratory validation studies prior to implementation of the regulations reasonable?

C. Technologies and Costs

A number of technologies have been used for the removal of VOCs in drinking water, as shown in Table 4. A more detailed discussion of applicable technologies and their costs are included in the cost and technology document. By definition, VOCs are compounds with a tendency to move from liquid phase to gas phase or, simply stated, evaporate. These chemicals also tend to have limited solubility in water. Engineers have designed treatment systems taking advantage of these physical-chemical properties.

Aeration and adsorption technologies have been shown to be effective. In certain cases, both technologies can be applied in series. Aeration or the introduction of air into water has been used routinely to remove gases from water, oxidize iron and hydrogen sulfide, and less frequently to remove objectionable tastes and odors. Most recently, aeration has been successfully applied in the removal of VOCs.

Another available technology is adsorption. Adsorption is the collection of a material at an interface or surface. Activated carbon in granular and powdered form has been used extensively for taste and odor control and most recently for the removal of VOCs from drinking water. All nine VOCs considered here can be removed from drinking water using aeration or activated carbon adsorption.

TABLE 4.—TREATMENT TECHNOLOGIES FOR VOC REDUCTION

	Estimated removal efficiency (percent)	Number of installations currently in operation in the U.S. for VOC removal
Aeration:		
a. Packed tower aeration	90–99.9	27
b. Multiple tray aeration	40–90	6
c. Diffused aeration	70–92	1
d. Spray aeration	75–90	1
e. Air lift pumping	40–97	2
f. Cascade aeration	(1)Unknown	1
Adsorption:		
a. Granular activated carbon	>99	4
b. Powdered activated carbon	50–90	1
c. Synthetic resins	>99	0
Other Treatment Options		
a. Point-of-use GAC	90–>99	1
. Ultraviolet-ozone	(1) Unknown	(1) Unknown.

1. Aeration.

When water containing a dissolved volatile or semivolatile compound is in contact with air, an equilibrium of molecules of the compound migrating from the water to the air (evaporating) and from the air to the water (dissolving) is established. Henry's Law describes the equilibrium relationship by stating that the concentration of a substance in the liquid phase (dissolved in water) is directly proportional to the partial pressure of the compound in the vapor phase (concentration in air). The coefficient of proportionally is known as Henry's Law Coefficient. By providing an environment where the concentration in air is low (for example, by continuously replacing semi-saturated air with fresh air) the system will tend toward as equilibrium condition of low concentration in water.

Because of their relatively low solubilities and high vapor pressures, VOCs have a natural tendency to migrate from water the air; that is, they have relatively high Henry's Law Coefficients. This tendency can be put to use in aeration treatment systems which enhance the migration, or transfer, by providing large water/air interfacial areas, large volumes of air relative to the volume of water treated and sufficient contact time for the transfer to occur.

Although many types of aeration devices are available, the packed column is the one which has been most widely applied for removal of VOCs from contaminated drinking water. In a packed column, contaminated water is pumped to the top of the column and cascades down through a bed of inert packing material. Uncontaminated air enters the bottom of the column and is driven or drawn upward through the packing, exiting at the top of the column. VOCs are transferred from the water to the air, resulting in treated water with very low VOC concentrations leaving the column at the bottom and air with elevated levels of VOCs discharged from the top of the column. Packing media are fabricated of various geometrical shapes or continuous elements, and are all designed to maximize the air/water contact opportuinity while minimizing the frictional resistance to the air flow (air pressure drop). Key design parameters are depth and type of packing, liquid loading and and air loading.

Because of the countercurrent flow pattern of air and water, very high removal efficiencies are possible. Rational design techniques are available which indicate, together with field data, that 90–99 percent removal of most VOCs can be obtained at reasonable depths of packing and moderate air to water ratios.

Other methods of aeration to remove VOCs are available, but they are generally less cost effective than packed tower aeration when high removal efficiencies are required. These methods include: spray aeration, diffused aeration, mechanical aeration, in-well aeration, multiple tray aeration, and cascade aeration. The nine VOCs listed here can be removed using aeration. Normally, a pilot-scale study is recommended to determine the proper operating conditions under each set of circumstances. Other factors which affect performance and suitability of aeration include water temperature, concentration of contaminants, maintenance of a chlorine residual, and the presence of iron or other unoxidized mineral contaminants. Good design practice would take these and other factors into consideration.

a. *Performance Potential of Aeration.* A number of successful applications of aeration have been documented in the literature and by EPA investigators as shown in Table 5.

TABLE 5.—EXAMPLES OF PACKED TOWER AERATION PERFORMANCE

Location	Major contaminant (raw water concentration range in µg/l	Air: water ratio	Percent removal	Treated water conc. (µg/l)
Wurthsmith, AFB MI.	TCE (50–8000)	25:1	99.9	4–8
Liberty, MO	TCE (36–69)		80	7–4
	1,1-DCE (11–22).			
Fairfield, NJ	Total VOCs		96	<10
	TCE.			
	(26–400) 1,1,1-TCA.			1–16
	(17–291) PCE			<1–12
	(<2–172) 1,2-DCA.			<1–7
	(<1–51)			<1–2
Rockaway, NJ	TCE (50–220)	144:1	99+	<1–2
Rockhill, NJ	TCE (45–95)	83:1	<99	<1
Browster, NY	PCE (420–470)	33:1	90	4–5
	TCE.			
	(30–48)			<1
Upper Merion, PA.	TCE (3–20)	11:1	94	<1–1.2
Warrington, PA	TCE (130)	40:1	97	4
Tacoma, WA	TCE (54–130)	62:1	95	7
	1,2 DCE (30–100).			2–5
	PCE (1.6–5.4)			<1
Hartland, WI	TCE (175)	50:1	99	<2

Source: Love, O.T. Jr., Fege, W.A., Carswell, J.K., Miltner, R.J., Clark, R.R., and Frank, A., "Aeration to Remove Volatile Organic Compounds from Ground Water," Draft Report, U.S. EPA Drinking Water Research Division, Cincinnati, Ohio, March 1984.
TCE: trichloroethylene
PCE: tetrachloroethylene
1,1,1-TCA: 1,1,1-trichloroethane
1,2-DCA: 1,2-dichloroethane

Love, et al. (1984) conducted a survey and reported that of the three dozen or so aeration systems installed, two-thirds used packed tower aeration. Table 5 displays some performance data from those systems in the survey using packed tower aeration. These data show that at least half of the systems were achieving greater than 99% removals at least part of the time, with treated water VOC concentrations in the low µg/l range. The variability of the raw water concentrations is also apparent in this data. Recent EPA studies using a pilot-scale packed tower aeration showed greater than 99 percent removals to be achievable at the over 30 sites which were studied.

Although removals of greater than 99.99 percent are theoretically achievable through physical/chemistry textbook calculations, maximum removal efficiency over a wide range of compounds using the best technology currently available under optimum conditions is approximately 99.9 percent for the compounds under consideration. Further, almost all information EPA has obtained on the performance of packed tower aeration indicates that 90 to 99+ percent removal has been achieved in actual practice. Unlike traditional concepts of pollutant removal, design of aeration for 99 percent removal is considered reasonable engineering practice; the incremental cost to achieve 95 to 99 percent as opposed to 90 percent is small when compared to the traditional concepts of biological oxygen demand (BOD) removal by biological treatment (i.e., it may cost X dollars to remove 90 percent and 2X dollars to remove an additional 5%). Thus, 99 percent removal of the nine VOCs using packed tower aeration is considered reasonable design and is possible under most circumstances. However, vinyl chloride is so easily removed by aeration that up to 99.9 percent reduction is considered achievable. The calculated Henry's Law Coefficient for vinly chloride is about ten to one hundred times higher than any of the other eight VOCs. This is because it has a high vapor pressure (it's a gas at ambient temperatures) and it has relatively low solubility in water. For these reasons, the removal of 99.9 percent of vinly chloride is considered to be achievable using packed tower aeration.

The above data and removal efficiencies are for ground water systems. Minimal data are available for removal of VOCs by packed tower aeration for surface water systems. Removal of VOCs from surface water might be more complex due to higher total organic carbon, colloidal particles, other matrix effects, and wider water temperatures variations. However, aeration would be expected to be an acceptable means of control; the different operating conditions would have some impact on the costs of operating the system.

b. *Feasibility/Reliability of Attaining Specific Levels.* Since packed tower aeration provides a fixed percent removal under a given set of conditions, variations in raw water concentrations will be accompanied by similar variations in treated water concentrations. While one would expect raw water concentrations of VOCs in ground water to be relatively constant or slow to change, actual data show that variations are not uncommon. Pumping patterns of the contaminated well and other wells in a well filed can also have significant effects on VOC concentrations. There is little long term data avaliable to judge how large a fluctuation in raw water VOC concentrations can be expected. This can be a particularly difficult problem in contaminated ground water since the cause and severity of the contamination are usually undefined. Large variations in concentrations have been experienced in some cases, while other water sources show concentration variations of only a few percent. This can be seen by examining the range of raw water concentrations in Table 5. In one case, the concentration of trichloroethylene ranged from 50 to 8000 µg/l.

Accounting for variations in monitoring the performance of packed tower aeration or GAC adsorption is a significant consideration for EPA is selecting best technology generally available and for any system considering such technology. As noted above, since packed tower aeration will provide a fixed percent removal of VOCs in the raw water; it follows that as the raw changes, so will the treated water. Some factor would need to be incorporated into the design to allow for these fluctuations. Monitoring treated or raw water is not considered economically feasible daily or weekly basis as commercial analyses at $150 to $200 per sample would result in significant costs. Moreover, some of the variation in the treated water concentration can be provided for in the design of the aeration system even though the actual variation in concentration is difficult to predict. Designs would almost likely be based upon measured concentrations of occurrence plus a presumed variability factor of 50 to 100 percent unless sufficient water quality data were available. In any event, public water systems must consider variations in designing their system and will be held accountable for meeting the MCL, despite variation in raw water.

c. *Secondary Effects of Aeration.* Transfer of VOCs from water to air might be a concern depending on the proximity to human habitation, treatment plant worker exposure, local air quality, local meteorological conditions, daily quantity of processed water and contamination level. In the example in Table 6, 500,000 gallons per day of water contaminated with trichloroethylene is treated using packed tower aeration. An air to water ratio of 33:1 is used to remove trichloroethylene from 50 µg/l in the raw water to 5 µg/l in the treated water. For purposes of air modeling, one hundred percent transfer from water to air is assumed. The stack height is five meters with an exit velocity of 0.4 meters per second and a stack gas temperature of 10°C. The site chosen was one described in Table 5 and all meteorological conditions are those for the geographic area of concern. The same model was run for a variety of geographic, meteorological conditions and water treatment parameters. The results for other examples were comparable to those presented here.

It is possible to consider the example shown in Table 6 in terms of projected

human cancer risks from inhalation exposure to vaporized VOCs. The individual risk of drinking two liters of water per day containing 50 μg/l of trichloroethylene would be calculated as 1.4×10^{-5} for a seventy year lifetime using a conservative multi-stage model (EPA, Health Effects Criteria Document for Trichloroethylene, see Final RMCLs). In Table 6 the highest air concentration projected is 0.1 μg/cubic meter and occurs 0.2 kilometers south of the source. The individual lifetime risk of breathing 20 cubic meters of air per day at this location (assuming a 50 percent air to blood transfer of trichloroethylene) is 1.3×10^{-7}. Since the concentration in air decreases rapidly as the distance from the source increases, the individual risk from air exposure also rapidly diminishes. Other examples were examined and EPA has determined that the risk resulting from exposure to VOCs in air from aeration of VOC contaminated water was lower than that resulting from drinking contaminated water. It was also apparent that in the cases examined, the amounts of VOCs added to air did not significantly increase risks from airborne contaminants.

TABLE 6.—AIR DISPERSION MODEL RESULTS FOR TRICHLOROETHYLENE EMISSIONS FROM A TYPICAL PACKED TOWER INSTALLATION

Wind direction	Air concentration (micrograms/cubic meter) of trichloroethylene at downwind distance (kilometers)				
	0.2	0.5	1.0	5.0	10.0
South	1.0×10^{-1}	2.2×10^{-2}	6.7×10^{-3}	4.9×10^{-4}	1.7×10^{-4}
West	6.5×10^{-2}	1.4×10^{-2}	4.4×10^{-3}	3.3×10^{-4}	1.1×10^{-4}
North	1.0×10^{-1}	2.2×10^{-2}	6.8×10^{-3}	5.0×10^{-4}	1.7×10^{-4}
East	4.1×10^{-2}	8.6×10^{-3}	2.6×10^{-3}	1.9×10^{-4}	6.4×10^{-5}

If necessary, control of VOC air emissions from packed tower aerators is possible using air phase GAC adsorption. Generally, air pollution control using GAC adsorption will roughly double the cost of packed tower aeration. This technology has been applied at a few installations in the United States, but is still considered to be in the developmental stages. It is necessary to reduce the relative humidity of the stack emissions to allow efficient adsorption of VOCs. This can be accomplished by heating the air prior to contact with the GAC. It should be noted that most applications of this technology are currently in use in industrial air pollution control where VOC concentrations are much higher than those being emitted from a packed tower operation.

d. *Cost of Packed Tower Aeration.* The estimated cost (in 1983 dollars) of 99 percent removal (e.g., from 500 μg/l to 5 μg/l) of the VOCs using packed tower aeration, is presented in Table 7 (cost for p-dichlorobenzene and 1,1,1-trichloroethane are based upon lesser removals as shown in the Table). These cost estimates are based on the size of equipment designed to provide the indicated removal efficiency and all material, electrical power and other items necessary to construct and operate the system. Comparisons with costs of actual installations have shown that the estimating procedure results in estimates which are generally higher than comparable actual cost. These costs are presented by system size category and include capital cost, annual operation and maintenance (O&M) cost, and total cost per thousand gallons (including annual O&M and amortized capital cost).

Table 7.—Cost for 99 Percent Removal (From 500 μg/l to 5 μg/l) of the Nine VOCs Using Packed Tower Aeration in August 1983 Dollars

Compound	Costs by system size category [1]		
	100–500 (0.037 mgd)	3,300–10,000 (0.95 mgd)	100,000–500,000 (36.8 mgd)
Trichloroethylene:			
Capital cost	69,000	264,000	4,789,000
Annual O&M cost	1,400	18,000	617,000
Total cost (cents per 1,000 gal)	79.0	15.5	9.4
Tetrachloroethylene:			
Capital cost	67,000	252,000	4,607,000
Annual O&M cost	1,200	15,000	513,000
Total cost (cents per 1,000 gal)	75.0	14.2	8.4
Carbon tetrachloride:			
Capital cost	66,000	249,000	4,536,000
Annual O&M cost	1,200	15,000	509,000
Total cost (cents per 1,000 gal)	75.0	14.0	8.3
1,2-Dichloroethane:			
Capital cost	84,000	461,000	10,221,000
Annual O&M cost	2,400	37,000	1,149,000
Total cost (cents per 1,000 gal)	101.0	28.5	18.7
Vinyl chloride:			
Capital cost	60,000	201,000	3,453,000
Annual O&M cost	900	11,000	377,000
Total cost (cents per 1,000 gal)	66.0	11.0	6.2
1,1-Dichloroethylene:			
Capital cost	64,000	229,000	3,975,000
Annual O&M cost	1,000	13,000	428,000
Total cost (cents per 1,000 gal)	71.0	12.5	7.1
Benzene:			
Capital cost	74,000	325,000	6,538,000
Annual O&M cost	1,700	23,000	781,000
Total cost (cents per 1,000 gal)	86.0	19.2	12.3
p-Dichlorobenzene (1,000 μg/l to 750 μg/l)			
Capital cost	51,000	146,000	2,469,000
Annual O&M cost	700	8,000	283,000
Total cost (cents per 1,000 gal)	56.0	8.1	4.6

Table 7.—Cost for 99 Percent Removal (From 500 μg/l to 5 μg/l) of the Nine VOCs Using Packed Tower Aeration in August 1983 Dollars—Continued

Compound	Costs by system size category [1]		
	100-500 (0.037 mgd)	3,300-10,000 (0.95 mgd)	100,000-500,000 (36.8 mgd)
1,1,1-Trichlorobenzene (500 μg/l to 200 μg/l)			
Capital cost	52,000	150,000	2,500,000
Annual O&M cost	700	8,500	290,000
Total cost (cents per 1,000 gal)	57.0	8.2	4.7

[1] Number of persons served and million gallons per day.

The raw water concentration of 500 μg/l as the basis for costs was chosen as an approximate 95th percentile worst case example of VOC contamination. Nearly all known contamination incidences are considerably less than this and actual costs would also be less. While the SDWA legislative history states that MCLs are to be based upon technologies affordable to large systems using relatively clean waters (H.R. Rep. 93–1185, 93rd Cong. 2d Sess. at 12–13 (1974)), the costs for the worst case situation presented in Table 7 are affordable to large systems; thus, costs of reducing VOCs from a lower concentration in the raw water would be less and similarly affordable. Costs do not increase proportionally if a system is designed for 99 percent compound removal compared to 90 percent removal. For example, costs for TCE removal at 90 percent would be 6.1 cents/1000 gallons compared to 9.4 cents/1000 gallons for 99 percent removal. This is roughly a 50 percent increase in costs for reaching a treated water concentration which is one-tenth that at 90 percent removal (i.e., 50 μg/l versus 5 μg/l).

2. Adsorption (Granular Activated Carbon)

Activated carbon removes organic contaminants from water by the mechanism of adsorption. Contaminant molecules migrate to the external surface of the carbon and then into the extensive pore structure in the interior of the carbon particle, where they are effectively removed from solution.

The capacity of activated carbon of a particular compound is a function of the type of carbon, the molecular structure of the compound, the concentration of the compound in the water, the presence of competing organic substances and a number of other factors. Because the effect of all factors on the adsorption capacity cannot be well defined, capacity is determined empirically, usually from laboratory equilibrium tests known as adsorption isotherms. Adsorption isotherms and other equilibrium tests permit the development of an equilibrium equation which relates the concentration of adsorbate (VOC) in the liquid phase to the concentration of adsorbate on the solid phase (concentration of VOC adsorbed per unit weight of activated carbon). This allows an estimation of the amount of carbon necessary to treat water with a given concentration of VOC under ideal circumstances.

Adsorption of VOCs from contaminated water is most likely and practically done by passing the water through a bed of granular activated carbon (GAC). As water passes downward through the bed, the GAC in the upper portions of the bed reach their equilibrium capacity and provide no further removal. Contaminant molecules penetrate deeper into the bed until they appear in the water leaving the bed. The appearance of detectable concentrations of VOCs in the treated water is known as breakthrough. When the concentration of the VOC in the treated water reaches an unacceptable level, the GAC in the bed is removed and replaced with either virgin carbon or reactivated carbon.

Critical design parameters are the empty bed contact time and throughput to exhaustion. Empty bed contact time (EBCT) is the volume of carbon in the bed divided by the hydraulic flow rate. Throughput to exhaustion signifies the specific volume treated at the point at which the bed is taken out of service (volume of water treated per unit volume of GAC in the bed). Throughput is expressed as bed volumes. The reciprocal of the throughput to exhaustion is the volume of carbon to be replaced per unit volume of water treated, or carbon usage rate.

Operating a carbon bed with short EBCT (e.g., 3–4 minutes) can result in rapid breakthrough and frequent removal and replacement or reactivation of the carbon with attendant high operating costs. Very long EBCT (30–45 minutes) allows long time periods between carbon replacement or regeneration cycles. A carefully designed pilot study can provide data which allow an engineering determination of the optimum GAC design parameters.

The majority of published carbon usage rates for VOC removal are for waters with low total organic carbon (TOC) concentrations. The data used in developing treatment and cost data for this proposed rule were also for low TOC waters. This was because VOC contamination has been characterized as predominately a ground water problem. The majority of ground water in the U.S. has low TOC content with south Florida being a notable exception. The significance of total organic carbon is that it competes with the VOCs for adsorption sites or the GAC. This leads to more rapid exhaustion of the GAC. Some studies have shown exhaustion for certain VOCs as early as three weeks when high levels of naturally occurring organic carbon are present. Carbon usage rates for high TOC water versus low TOC water have been estimated to be two to six times higher. Carbon replacement costs could be at least as much as six to eight times higher for surface water systems compared to ground water systems.

Table 8 Illustrates some pilot data for various locations where time to breakthrough was reported. In these cases, carbon was removing VOCs for at least 12 months before the first trace of VOC was seen in the treated water. There is some limited evidence that backwashing of GAC beds can disrupt the adsorption wave front and permits premature breakthrough, although the ultimate capacity is not diminished. This problem should be considered in the design and operation of GAC adsorption systems.

TABLE 8.—BREAKTHROUGH PERFORMANCE OF GRANULAR ACTIVATED CARBON ADSORPTION

Location	Raw water concentration	Empty bed contact time (minutes)	Treated water concentration (µg/l)	Approx. time to breakthrough (i.e., detection)(months)
New Jersey	194 µg/l PCE	10.5	<1	22
Pennsylvania	20–30 µg/l TCE	7.5	<1	20
New Hampshire	120–276 µg/l TCE	9	<1	18
New Jersey	23 µg/l 1,1,1-TCA	18	<1	13
Connecticut	1–214 µg/l 1,1,1-TCA	8.5	<1	12

After VOCs begin to appear in the treated water and the concentration is approaching the MCL, the GAC must be replaced or regenerated. Small systems will probably find that replacement is more economical. GAC replacement services are available from activated carbon suppliers. Large systems may determine that on-site reactivation is cost-effective. In these situations the carbon may be regenerated by the supplier or disposed of at an approved disposal site. Various types of equipment are available to accomplish thermal reactivation of GAC.

Two other methods of adsorption include the use of powdered activated carbon (PAC) and synthetic resins. PAC has limited applicability due to low adsorption; however, PAC may be useful for temporary application or cases where the standard is only marginally exceeded. Low rates of removal occur because PAC moves along with the water column and comes to equilibrium with the effluent concentration. Synthetic resins have shown promise in experimental use, but they are not available on the commercial market and are currently very expensive to produce. For these reasons, these two methods are not applicable to the wide varieties of VOC contamination anticipated that would be encountered.

a. *Performance Potential/Feasibility of GAC.* There are published performance data for VOC removal rates from pilot studies. All the VOCs except vinyl chloride can be removed using GAC adsorption. GAC should lower the concentrations of the other eight VOCs to below the limits of detection for a period of time which will depend primarily upon the EBCT, the influent concentration and the adsorption characteristics of the individual compound. The carbon usage rates for benzene and 1,2-dichloroethane are significantly higher than the other six compounds, but it is still feasible to remove them using carbon adsorption. Engineering studies can generate data to determine the EBCT which will provide the optimum balance between capital and operating costs. When the treated water VOC concentration approaches the MCL, the spent carbon must be removed and replaced with either virgin or reactivated carbon. GAC can be used to remove VOCs from surface water supplies, but the background organics in many surface waters could result in earlier breakthrough of VOCs resulting in slightly higher costs. GAC might be especially applicable when a water supply is or may potentially be contaminated with non-volatile organics as well as VOCs as GAC does remove a wide variety of organic compounds.

GAC performance should be monitored carefully to detect the breakthrough of VOCs and to determine when the GAC should be removed from service.

b. *Secondary Effects of GAC Adsorption.* Thermal reactivation of GAC in a gas or oil fired unit may result in the discharge of particulates and combustion products of both the fuel and adsorbed organics. Reactivation can also be accomplished using electrical resistance furnaces with steam injection, which decreases potential air pollutants. In either case, reactivation systems are always supplied with air pollution control equipment, such as afterburners, cyclone dust collectors, and wet scrubbers. For this reason, emissions from reactivation operations were not considered significant enough to be of major concern in developing this proposal.

Systems must properly dispose of spent GAC and backwash from contactors. Disposal of spent GAC is not anticipated to be a problem, since a number of disposal methods are available for similar wastes (e.g., GAC used in wastewater treatment). Backwash water from contactors can be treated like sand filter backwash. These methods include recycling of backwash water, discharge to a sanitary sewer, or treatment and disposal to surface waters (NPDES requirements must be met). Both solid and liquid waste disposal requirements of GAC treatment can be met with existing technology and should not present a significant problem for affected utilities.

Systems must also maintain the microbiological quality of water treated with GAC. Properly designed and operated disinfection facilities should be provided in all cases as a barrier to microbial contaminants entering the distribution system. With proper operation of GAC contactors (including backwashing) and proper post disinfection, microbiological quality degradation should not occur.

c. *Cost of Controlling VOCs using GAC.* The costs of removing VOCs using GAC adsorption were estimated assuming steel pressure vessel contactors for system sizes with less than two million gallons average daily flow and concrete gravity flow contactors for larger systems. EBCT used for all design calculations was 10 minutes. The construction cost of the steel pressure vessels were developed using manufacturer's quotes for equipment and standard cost estimating procedures for installation, buildings, electrical, and instrumentation. The construction costs for concrete gravity flow contactors were developed using an EPA cost estimating equation. Capital cost were then calculated using the following mark up factors: 12 percent for sitework, 15 percent for engineering, 15 percent for contractor overhead and profit, and 15 percent for contingencies. Carbon usage rates were determined by extrapolating the data of Love and Miltner, 1983 (Environmental Science and Engineering, 1984). Operation and maintenance costs were then determined using the EPA cost estimating equations. Costs are presented in Table 9 below for 99% removal except for 1,1,1-trichloroethane and p-dichlorobenzene which are costed at lesser percentage removals because of their higher RMCLs/MCLs.

TABLE 9.—COST FOR 99 PERCENT REMOVAL (FROM 500 μG/L TO 5 μG/L) OF THE NINE VOCs USING GRANULAR ACTIVATED CARBON ADSORPTION IN AUGUST 1983 DOLLARS

Compound	Costs by system size category [1]		
	100–500 (0.037 mgd)	3,300–10,000 (0.95 mgd)	100,000–500,000 (36.8 mgd)
Trichloroethylene:			
Capital cost	24,000	240,000	9,000,000
Annual O&M cost	4,500	86,000	710,000
Total cost (cents per 1,000 gal)	57.0	34.0	14.0
Tetrachloroethylene:			
Capital cost	24,000	240,000	7,700,000
Annual O&M cost	2,800	45,000	400,000
Total cost (cents per 1,000 gal)	45.0	22.0	11.0
Carbon tetrachloride:			
Capital cost	24,000	240,000	9,800,000
Annual O&M cost	5,700	85,000	930,000
Total cost (cents per 1,000 gal)	66.0	34.0	17.0
1,2-Dichloroethane:			
Capital cost	24,000	249,000	11,000,000
Annual O&M cost	9,400	150,000	1,500,000
Total cost (cents per 1,000 gal)	93.0	52.0	23.0
Vinyl chloride:			
Capital cost	NA	NA	NA
Annual O&M cost	NA	NA	NA
Total cost (cents per 1,000 gal)	NA	NA	NA
1,1-Dichloroethylene:			
Capital cost	24,000	240,000	9,100,000
Annual O&M cost	4,600	90,000	740,000
Total cost (cents per 1,000 gal)	58.0	35.0	15.0
Benzene:			
Capital cost	24,000	236,000	17,200,000
Annual O&M cost	15,700	258,000	2,800,000
Total cost (cents per 1,000 gal)	150	83.3	37.6
p-Dichlorobenzene (1000 ug/1 to 750 ug/1)			
Capital cost	24,000	240,000	5,100,000
Annual O&M cost	1,900	22,000	230,000
Total cost (cents per 1,000 gal)	38.0	15.0	6.9
1,1,1-Trichloroethane (500 μg/l to 200 μg/l):			
Capital cost	24,000	240,000	10,000,000
Annual O&N cost	6,600	100,000	1,100,000
Total cost (cents per 1,000 gal)	73.0	38.0	18.0

[1] Number of persons served and million gallons per day.

3. Other Technologies

Other technologies can be considered for possible control of VOCs in drinking water. These include ultraviolet radiation and ozone, non-treatment alternatives such as regionalization, alternate source, well field management, and point-of-use/entry treatment (single tape/whole house). They are discussed in more detail in the Cost and Technology document.

4. Best Technology Generally Available

For purposes of determining the appropriate levels for MCLs, EPA must identify the best technology generally available (BTGA). The SDWA provides in section 1412(b)(3):

> The maximum contaminant level specified in a revised national primary drinking water regulation for a contaminant shall be as close to the recommended maximum contaminant level . . . as feasible . . . [T]he term "feasible" means feasible with the use of the best technology, treatment techniques, and other means, which the Administrator finds are generally available (taking costs into consideration).

In addition, as discussed in Section IV below, one of the purposes of the rule being proposed today is to identify pursuant to section 1415(a)(1)(A) of the SDWA, the best technologies, treatment techniques or other means that the Administrator of EPA has determined to be generally available, taking costs into consideration. The analysis in this section supports both sections 1412 and 1415 findings of best technology generally available.

The determination of BTGA is essentially a two step process:

(1) Engineering assessment of technologies and other means that may be used for removing the pertinent contaminants.

(2) Assessment of the costs of the technology to determine their affordability to public water systems and consumers and the levels of contaminants removed.

The first step in this process is to list all technologies which are commercially available for removal of the contaminants. The performance potential of these technologies can then be determined in terms of relative removal efficiencies. Table 10 lists those technologies identified for VOC removal.

From this list, the best technologies generally available were determined by a thorough review of existing data to evaluate which technologies have the highest efficiencies of removal, are designed specifically for VOC removal, are compatible with other types of water treatment processes, are available as manufactured items or components, are not limited to application in a particular geographic region, have integrity for a reasonable service life as a public work are reasonably affordable by large metropolitan or regional systems. Also, EPA must consider "all technology that can be mass produced and put into operation in time for implementation of (the revised) regulations."

From the list in Table 10, packed tower aeration and GAC adsorption were determined to meet the engineering criteria for BGAT. Detailed cost assessments were then made of capital, O&M, and total annual costs of installation and operation of GAC and packed tower aeration. The costs to public water system and consumers in medium and large systems were then assessed and determined to be reasonable (see Tables 8, 9 and 12). EPA is also aware that a number of small systems have already installed these technologies and found them to be affordable. Because these technologies are affordable by small systems, economies of scale would also make them affordable to medium to large size systems. The increased cost is expected

to be passed to the consumer either as a water rate increase or as a tax increase.

It has been suggested that EPA should specify different BTGA for small systems. In the case of the technologies available for VOC removal, EPA does not feel this is necessary. The technologies (aeration and adsorption) are effective and appropriate for any size of system, both from a design and an operational perspective. Of course, a system may choose any means of compliance; it need not use aeration or adsorption.

Table 10

Unit Processes and Other Means Considered in Determining BTGA

Aeration
Waterfall Aeration
- Packed tower aeration
- Multiple tray aeration
- Cascade aeration
- Spray aeration

Diffused Aeration
- In existing vessels or tanks
- In well (includes air-lift pumping)

Mechanical Aeration
Adsorption
Granular Activated Carbon
Powdered Activated Carbon
Strong Base Anion Exchange Resins
Ultraviolet-Ozone Oxidation
Reverse Osmosis
Home Treatment Devices (Point-of-entry or Point-of-Use)
Reverse Osmosis
GAC Adsorption
Aeration
Non-Treatment Alternatives
Well Field Management
Regionalization Alternate Source
Bottled Water

a. *BTGA: Packed Tower Aeration; GAC Adsorption.* Packed tower aeration is considered BTGA because: (1) It can achieve a high level (99%) or more of VOCs removal under all anticipated conditions, (2) its application is not limited by climatic conditions such as temperature or geographic conditions such as space, (3) it is compatible with other forms of water treatment, (4) it can be installed either at the well head or in a central treatment plant, (5) technologies are available to handle any side effects (e.g., air pollution or increased corrosivity), (6) the equipment is commercially available and typical of that used by the water industry, (7) it can be designed for operation for a reasonable number of years before replacement would be needed, (8) it is reasonably affordable by large public water systems, (9) it does not require any pre-existing structures (e.g., basins for diffused aeration), and (10) it has been successfully applied to the removal of VOCs in at least twenty-four full-scale plants in the U.S.

GAC adsorption is considered BTGA because: (1) It can achieve a high level (up to 99.9%) of removal of several VOCs (except, e.g., vinyl chloride, and to lesser extents benzene and 1,2-dichloroethane), under all anticipated conditons, (2) its application is not limited by climatic or geographic considerations, such as space, (3) it is compatible with other forms of water treatment, (4) it can be installed either at the well head or in a central treatment plant, (5) technologies are available to regenerate used carbon or dispose of it and any potentially adverse side-effects (i.e., bacteria) can be controlled using existing technology, (6) the equipment is commercially available and typical of that used in the water industry, (7) it can be designed for economical life, (8) it is reasonably affordable by large public water systems, (9) it does not require preexisting structures (e.g., basins and filters for PAC), and (10) it has been successfully applied to the removal of VOCs in at least five plants in the U.S.

Certain of the other technologies listed in Table 11 may be appropriate for use in specific circumstances but do not meet the above criteria. These include:

b. *Other Technologies: Ultraviolet—Ozone Oxidation.* There is some limited experimental data on the usefullness of ultraviolet radiation-ozonation systems to remove VOCs from drinking water. This technology is available, but is quite new and is not in general use in the water industry. Insufficient data are available upon which to judge the performance and the costs of treatment.

c. *Other Technologies: Reverse Osmosis.* There are limited data on this technology's application for removing VOCs. Membrane fouling is a real concern that limits the potential use of this technology. Some membrane materials are also rapidly permeated by the VOCs and rapidly become ineffective. Only limited cost data could be developed on the use of reverse osmosis and reliability of the process is questionable.

d. *Other Technologies: Non-Treatment Alternatives.* These include well field management, alternate source, and regionalization. Since these depend on local geology and geography, EPA cannot say they are generally available to most systems with VOC contamination.

e. *Other Technologies: Point-of-Use/Point-of-Entry Treatment Devices.* Point-of-use devices treat the drinking water in the home, providing treated water at a single tap. They are installed as faucet mounted devices or under-the-sink line bypass devices. Point-of-entry devices treat the water as it enters the home and provide treated water throughout the entire home. Two types of treatment have been investigated and reported in the literature as applicable to point-of-use/entry treatment to remove VOCs. These types of treatment are reverse osmosis and granular activated carbon (GAC) adsorption.

The effectiveness of point-of-use devices has been studied for reverse osmosis (Sorg, Thomas J. and Love, O. Thomas, "Reverse Osmosis Treatment to Control Inorganic and Volatile Organic Contamination, *Proceedings*, Preconference Seminar: "Experiences with Ground Water Contamination," Annual AWWA Conference and Exposition, Dallas, Texas, June 1984) and granular activated carbon adsorption (Bellen and Gottler, "Point of Use Reduction of Volatile Halogenated Organic Contaminants from Drinking Water," First Report, U.S. EPA, MERL, Cincinnati, Ohio, 1984). Reverse osmosis using cellulose, nylon amide, and thin film membranes was found to have limited effectiveness due to permeation of the membranes by a variety of VOCs. Based on this preliminary study, reverse osmosis cannot be considered an effective technology for VOC removal. On the other hand, studies of GAC adsorption point-of-use devices have found that a number of commercially available devices effectively removed some of the VOCs of concern. These VOCs included trichloroethylene, tetrachloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, 1,1-dichloroethane, 1,1-dichloroethylene, and chloroform. Breakthrough (defined as detectable concentrations of VOCs) was not observed in some devices in use for up to 24 months. This study also confirmed an increase in total bacterial plate count in the treated water previously described by other authors. However, it was noted that flushing the GAC unit reduced the bacterial concentration to near background.

GAC adsorption point-of-use/entry treatment devices are not BTGA but could be considered acceptable technology to meet MCLs under certain conditions as specified below. These devices are not BTGA because it is difficult to monitor the reliability of treatment performance in a manner comparable to central treatment. In addition, point-of-use devices only treat the drinking water at the single tap.

The SDWA provides authority for EPA to establish the conditions under which treatment devices may be used, if necessary to assure protection of public health. Section 1401(1) of the Act states that primary drinking water regulations are to contain "criteria and procedures to assure a supply of drinking water

which dependably complies with . . . maximum contaminant levels; including quality control and testing procedures to insure compliance with such levels and to insure proper operation and maintenance of the system." The legislative history also makes clear that EPA has authority to prescribe operating requirements where necessary to assure safe drinking water and that these requirements should be as limited as possible. H.R. Rep. No. 93–1185, 93rd Cong. 2d Sess. at 14–15 (1974).

EPA believes that because point-of-use/point-of-entry devices are different from cental treatment alternatives, and present a potential that public health will not be protected to the same degree as central treatment it is important to establish minimum criteria for operation, maintenance, and testing of these devices. Therefore, EPA is proposing to establish the conditions listed below as the minimum requirements for systems using point-of-use/point of entry devices. These requirements are limited to those necessary to assure that the water supplies dependably compies with the MCL.

If point-of-use/entry devices are to be considered as an acceptable technology, to meet the proposed VOC MCLs, the approving primacy agency (State or EPA) would have to assure that the following conditions are met:

(1) Central Ownership and Control. It would be the responsibility of the public water system to own, operate, and maintain all parts of the treatment system (i.e., the treatment device). This appears appropriate and necessary to ensure adequate control of the treatment device so that it is working properly.

(2) Effective Monitoring and Surveillance. The utility would develop a plan and obtain State approval for a monitoring scheme before point-of-use/entry devices are installed for compliance. This monitoring scheme must provide health protection equivalent to a monitoring scheme for central water treatment.

Monitoring and surveillance would also include physical measurements and observations such as total flow treated and the mechanical condition of the treatment equipment. Monitoring and surveillance are a central part of the NPDWRs to ensure that MCLs are complied with. Because point-of-use/entry schemes are fundamentally different, a unique monitoring scheme must be devéloped.

(3) Effective Technology Must Be Property Applied. There are no generally accepted standards for the design and construction of these devices. The State would have to require adequate certification of performance, field testing, and a rigorous engineering design review. This condition is needed because of the variety of devices that might be employed.

(4) The Microbiological Safety of the Water Must be Maintained. The design and application of these devices must consider the tendency for increases in bacterial concentrations in water treated with activated carbon. It may be necessary to use frequent backwashing, post-contactor disinfection, and monitoring to ensure that the microbiological safety of the water is not compromised. This condition is believed necessary to protect health from any bacterial threat the devices may present.

(5) All Consumers are to Be Protected. Every building connected to the system must have the device installed, maintained, and adequately monitored. The State must be assured that every building is covered by treatment and monitoring, and that the rights and responsibilities of the utility customer convey with title upon sale of property. Individual public water fountains not in or connected to a building need not have a point-of-use/entry device.

(6) There Must Be No Significant Increase in Risk Over Centrally Treated Water. Under the plan approved by the State, point-of-use/entry devices must provide health protection equivalent to central treatment. This would include determination if the VOC concentrations are high enough to create a significant risk from dermal and respiratory exposure and any other sources of exposure except individual public water fountains.

These last two conditions [i.e., (5) and (6)] are central to the criteria under which point-of-use/entry devices could be approved for use: there is to be adequate protection of human health from the treatment devices.

If a primacy State wishes to allow systems to use point-of use devices to comply with an MCL, it must adopt regulations which are no less stringent than EPA's regulations. Of course, States may be more stringent and not allow systems to comply using point-of-use/entry devices. (These States must adopt regulations prohibiting point-of-use/entry devices; this decision will not jeopardize primacy.)

5. Bottled Water. EPA has rejected use of bottled water as best technology generally available. Bottled water does not provide the same level of protection as central treatment, as persons often choose not to drink bottled water. In addition, there could be problems with access to delivery of bottled water. Thus, bottled water is also not an acceptable permanent means of meeting the MCL requirements. EPA is proposing that bottled water not be considered an acceptable means of meeting MCLs on a permanent basis. However, bottled water meeting the MCLs may be considered as an emergency or interim measure to prevent an unreasonable risk during the time between detection of an MCL violation and compliance through other means.

Public comments and information/data are requested on the availability of technologies and costs of these technologies for control of VOCs. Specific comments are requested on the question of considering: (1) Point-of-use/treatment devices, (2) point-of-entry treatment devices, and (3) bottled water as BGAT or as acceptable technologies. Are these appropriate under the SDWA to use in achieving MCL compliance by public water systems?

D. Selection of MCLs

Provided below is a brief summary of the pertinent factors considered in determining the proposed MCLs.

1. *Analytical Methods*

As noted above, three methods are available for the determination of VOCs in drinking water. The EPA approved methods involve the use of gas chromatography (GC) with either a conventional detector or a mass spectrometer (GC/MS). These analytical methods have the required scope, sensitivity and reliability, and these are experienced laboratories available to conduct the analyses. The technology employed is similar to that used for the analysis of trihalomethanes, however it is being applied to levels about 1 or 2 orders of magnitude below the TTHM MCL. The costs of sample analysis appear to be about $150–$200 per sample.

For purposes of this proposal, the PQL for the VOCs is 5μg/l, except for vinyl chloride for which the PQL of 1 μg/l. These PQLs represent the lowest level achievable by about 90% of good laboratories under routine operating conditions. The level measured would be expected to be within ± 40% of the true value at levels less than 10 μg/l and ± 20% above 10 μg/l. These PQLs are primarily based upon PE studies. Reliability of analytical results is expected to decrease as laboratories attempt to measure lower and lower concentrations. Data on day to day performance in most commercial laboratories are not available, but it would be expected in many cases to be poorer than the EPA and State (or

commercial) laboratories participating in the PE studies.

2. *Availability/Performance of Treatment Technologies*

Two technologies, packed tower aeration and granular activated carbon (GAC) adsorption, are specifically suitable for VOC control, have high theoretical and empirically determined removal efficiencies (90–99% or more), have been used by drinking water systems in the U.S., and their costs are reasonably affordable when used by large systems. These technologies are thus considered best technologies generally available for determination of the MCLs.

Reasonable removal efficiencies for packed tower aeration are up to 99 percent for eight of the VOCs and up to 99.9 percent for vinyl chloride. In most cases, GAC can achieve VOC levels below detection until breakthrough which could be 12 months or longer. Consideration include: (1) The variability of VOCs in the raw water (± 50–100% variation in raw water concentration is a reasonable estimate); and (2) the feasibility of performance monitoring at $150 to $200 per sample.

3. *Levels of VOC Occurrence*

As stated above, application of the available technologies will either achieve a concentration lower than the analytical detection limit (e.g., via GAC) or remove up to 99 percent of the raw water concentration. Legislative history suggests that MCLs should be based upon treatment afforable by large systems using relatively clean intake water. In order to project an estimate of expected VOC contamination, positive occurrence results from EPA and State VOC surveys have been pooled (Table 11) and for each VOC, the median and 95th percentile concentrations determined. The latter concentration represents the concentration below which 95 percent of the positive sample results would occur. For example, about 238 or 95% of 251 selected positive samples were contaminated with tetrachloroethylene at concentrations between the MDL (probably 0.5 μg/l) and 175 μg/l. Median levels are usually well below 5 μg/l. If the median level were considered to represent the "relatively clean intake water" suggested in the legislative history, application of aeration technology (i.e. 99% removal) would result in levels below the PQLs.

The surveys included both public water systems samples and a few ground water samples not necessarily used for drinking water; the latter were often collected near suspected spill or contamination sites. The information in Table 11 represents only the positive portion of the samples measured. This provides a way to project an upper bound on the maximum contamination that 95 percent of the community water systems could expect before applying treatment.

TABLE 11.—VOC RAW WATER LEVELS

VOC	No. of contamination incidences	Median: 50th percentile μg/l	95th percentile μg/l
Trichloroethylene	257	4.6	300
Tetrachloroethylene	251	3.3	175
Carbon Tetrachloride	134	2.6	40
1,2-Dichloroethane	59	3.2	100
1,1-Dichlorbethylene	47	3.5	50
Benzene	61	1.8	30
Vinyl chloride	15	4.3	70
p-Dichlorobenzene	57	0.3	4
1,1,1-Trichloroethane	195	3.5	143

4. Other Technical Feasibility Factors

Air pollution due to aeration does not appear to be a problem in the vast majority of cases. Assessments of air emissions of VOCs have shown potential levels in the air to be negligible. Some States have indicated that aeration of VOCs without air pollution control is not a viable alternative in their State. Air pollution control using gas phase carbon adsorption is available, but total production costs would approximately double. In these cases, the systems would probably choose GAC adsorption as the mode of water treatment.

5. Costs of Treatment

The costs for the removal of the nine VOCs are considered reasonable for medium and large systems; costs vary from 5 to 15 cents/1000 gallons for aeration and from about 10 to 85 cents/1000 gallons for GAC adsorption. The annual cost per family is presented in Table 12. Costs for small systems are high (38–150 cents/1000 gallons) but again costs are worst case scenarios and actual costs would probably be less. In addition, a number of small systems have installed aeration or GAC for control of VOCs which would indicate that these technologies are affordable.

Total national costs are also shown in Table 12 which is based upon the use of all occurrence data and projecting the number of systems that would need to install treatment at three alternate levels for the MCLs. The increase in total national costs becomes larger if MCLs are set at 1 μg/l as opposed to 5 μg/l or 10 μg/l. At MCLs of 1 μg/l, many more groundwater systems would need to install treatment. In addition, many surface water systems would also need to install treatment because when surface water systems have VOCs, they are generally at concentrations less than 5 μg/l.

TABLE 12.—COSTS IMPACTS OF MCLS AT VARIOUS LEVELS

MCL Opts. μg/l	Estimated # systems impacted	National cost ($ millions)		Annual cost per family per size of system (dollars per year)			
		Total capital	Annual	Very small	Small	Medium	Large
1	3,800	1,300	100	96	47	12	8
5	1,300	280	21	91	41	12	3
10	800	150	11	90	42	11	1

E. Proposed MCLs

EPA is proposing to set the MCLs based upon: (1) 99+ percent removal by packed tower aeration (99.9% for vinyl chloride) and granular activated carbon and (2) the capabilities of laboratories to measure VOCs within reasonable limits of prevision and accuracy (i.e., the PQL is 5 μg/l for eight VOCs and 1 μg/l for vinyl chloride). Doubling the median values in Table 11 to allow for 100 percent raw water variability and reducing that amount by 99% would result in MCLs below the PQLs in every case. In this analysis, median and lower values would represent the SDWA requirement to set MCLs based upon relatively clean intake waters. Looking at a worst case scenario, sample calculations are shown below based upon raw water levels corresponding to the 95th percentile of the positive EPA and State occurrence data in Table 11 for each VOC. An assumed raw water concentration fluctuation of 100 percent was factored into the calculations below (i.e., the 95th percentile of the occurrence data was increased by 100% to determine the appropriate raw water concentration).

	μg/l
Benzene:	
95th percentile	30
plus 100% variation	60
99% removal	0.6
PQL	5
MCL	5

	µg/l
Vinyl chloride:	
95th percentile	70
plus 100% variation	140
99.9% removal	0.14
PQL	1
MCL	1
1,1-Dichloroethylene:	
95th percentile	50
plus 100% variation	100
99% removal	1.0
PQL	5
RMCL	7
MCL	7
Trichloroethylene:	
95th percentile	300
plus 100% variation	600
99% removal	6
PQL	5
MCL	5

EPA is proposing to set the MCLs equal to the RMCLs for 1,1-dichloroethylene, 1,1,1-trichloroethane and p-dichlorobenzene as the RMCLs are higher than the PQL and levels achievable by BTGA. The remaining MCLs are set based on the levels achievable by BTGA and the PQL. The levels of 5 µg/l and 1 µg/l (for vinyl chloride) are clearly achievable on the basis of treatment technologies and limits of analytical detection, taking precision/accuracy into account. The 95th percentile occurrence data were used to demonstrate that even in the worst case situations, the BTGA could achieve the PQL or the RMCL. Aeration and GAC adsorption are effective at any range of concentration anticipated in drinking water. Engineering design could certainly remedy the situation such as in the above example for trichloroethylene; that is, the treatment methods could be altered within their design parameters to remove the additional 1 µg/l. The proposed MCLs for the VOCs are presented Table 2.

F. Applicability to Certain, Non-community Water Systems

MCLs in the Interim Regulations that posed chronic (long-term) health risks do not apply to non-community water systems. MCLs, such as total coliforms and nitrate, that posed acute (short-term) health risks did apply to non-community systems. Non-community water systems are those that serve transient populations, such as campgrounds, parks, restuarants, gas stations and schools.

The basis for regulating non-community systems in this manner was that transient populations used these types of systems and thus, long-term health risks would not exist. However, since implementation of the Interim Regulations, experience has shown that certain types of non-community systems serve the same consumers over long periods of time, such as schools and factories. The chronic health risks to consumers in these types of systems would be similar to residential populations. Therefore, EPA is considering amendment of the definition of community water systems such that non-community systems serving such populations are included. While regulatory language is not proposed in the back of this notice, EPA may include in the final regulations. The effect of this amended definition would be that the Revised Primary Drinking Water Regulations would apply to such systems as schools, factories, and day care centers; MCLs monitoring, reporting and public notice would apply for the VOCs and other contaminants that will be included in the Revised Regulations. The definition of community water systems would include non-community systems that serve at least 25 non-transient people over 6 months a year, and it is estimated that 10 to 15 percent of 158,000 non-community water systems would be included. In definition of a community water system would be amended to read as follows:

> Community Water Systems means a public water system which serves as least 15 service connections used by year-round residents or regularly serves at least 25 of the same persons over six months per year.

Six months would be included as a reasonable projection of what period could represent a long-term health risk; EPA requests comment on this specific time period and this definition. Public comments are requested on this approach that would include such systems as schools and factories in the definition of community water systems in the Revised Primary Drinking Water Regulation, and the specific definition of what would constitute this kind of system.

IV. Best Technology Generally Available for Section 1415 Variances

Today's rule proposes a new section 142.61, "Variances from the maximum contaminant level for volatile organic chemicals." This section implements section 1415(a)(1) of the SDWA for VOCs. Under this section of the Act, EPA or the primacy State may grant variances from national primary drinking water regulations if certain conditions are met. These conditions include: (1) An inability to meet the MCLs despite application of best technology which the Administrator finds are generally available, (2) a finding that the variance will not result in an unreasonable risk, (3) a compliance schedule, (4) implementation of such additional control measures as may be required, and (5) public notice of the proposed variance and opportunity for a hearing.

The purpose of today's proposed regulation under Section 1415 is to identify the "best technologies, treatment techniques, or other means that the Administrator finds are generally available (taking costs into consideration)." SDWA section 1415(a)(1)(A). These are the technologies that the system must install or agree to install as a condition of receiving the variance. This regulation is modeled on the variance rule promulgated for trihalomethanes in 40 CFR 142.60 (48 FR 8406, February 28, 1983).

EPA believes that packed tower aeration and granular activated carbon adsorption are best technologies generally available, considering costs under section 1415. EPA reached this conclusion based on the analysis in section III of this notice. Subsection (a) and (b) of proposed § 142.61 specify the two best technologies generally available and that they must be used unless they are not technically appropriate or technically feasible for the system. In any event, systems shall be required to evaluate alternative treatment methods specified in subsection (c) as part of the schedule of compliance. These treatment alternatives are discussed in section III. If a method is technically feasible, economically reasonable, and will achieve removals commensurate with the costs incurred, the Administrator or primary State will require use of that method (see subsection (d)).

If a State intends to grant variances to the VOC regulations, it must issue variances that are no less stringent than those issued under this section. States intending to issue these variances would have to adopt comparable authority to receive or retain primary enforcement authority under section 1413 of the Act.

EPA invites comment on all aspects of this proposed variance regulation. In particular, EPA solicits comment on the findings of best technology generally available under section 1415 and the specification of alternate technologies.

V. Compliance Monitoring Requirements

Compliance monitoring requirements are being proposed for the purpose of determining if public water systems are distributing drinking water that meets the MCLs. As a class of chemicals, VOCs are included in the second tier of the three tiered approach presented in the Phase II ANPRM published on October 5, 1983 (48 FR 45502). The tiers are as follows:

Tier I—Those which occur with sufficient frequency and which are of sufficient concern to warrant national

regulation (MCLs) and consistent monitoring and reporting.

Tier II—Those which are of sufficient concern to warrant national regulation (MCLs) but which occur at limited frequency, justifying flexible national minimum monitoring requirements to be applied by State authorities.

Tier III—Those which would not warrant development of a regulation but for which non-regulatory health guidance could be provided to States or water systems.

The three tiered approach was developed to provide a framework for developing MCLs and monitoring requirements according to the significance of the contaminants in drinking water, the extent of contamination, and the predictability of occurrence or potential occurrence in drinking water.

Tier II includes those contaminants which may sometimes be predictable in drinking water based upon a multiplicity of factors such as geological conditions, type of source, historic record, or proximity of sources of drinking water contamination such as industries and hazardous waste sites. Cases such as these appear to warrant conferring discretion on States so that activities can be tailored to regional conditions. Thus, although compliance with the MCL would be required in all cases, States are being provided flexibility in establishing monitoring requirements within minimum federal requirements.

In the development of VOC compliance monitoring requirements, EPA considered: (1) The differences between ground and surface water systems, the (2) collection of samples which are representative of consumer exposure, the economic burden associated with the sampling and analytical costs, and (4) the limited occurrence of VOCs and the need for States to take an active role in requiring increased monitoring over the federal minima. EPA has determined that the sampling and analytical costs are reasonable and that there are sufficient analytical laboratories capable of handling sample analyses in the scheme proposed if the initial monitoring requirements are phased-in over a period of several years.

Surface and ground waters have been considered separately because: (1) The sources and mechanisms of contamination for these systems are different, (2) the overall quality of ground waters tends to change more slowly with time than does the quality of surface waters, and (3) ground water contamination is usually a localized problem confined to one or several wells within a system. For ground water systems, sampling will be done at entry points to the distribution system since VOC contamination of the water reaching the consumer is not expected to increase within the distribution system. However, source monitoring results may be used to decrease the number of samples taken at entry points to the distribution system or to reduce the frequency of monitoring for the determination of compliance with the MCL. Reductions in the number of samples or frequency of monitoring, if appropriate, will be determined by the primacy agency.

EPA has identified situations where monitoring should be more frequent. The probability of contamination of a water supply increases when one or more of the following conditions exist: (1) Proximity to large population areas, (2) nearby commercial or industrial use of VOCs, and (3) lack of protection of the water source by natural factors or land use control. It is important to identify industrial, commercial or municipal facilities that handle wastes or use solvents and to locate abandoned waste sites. Surface water systems may be protected by land use restrictions or by remotness of the sources from VOC-based activities. Ground water systems may be protected naturally by geological formations above the aquifers that are impermeable to VOCs used or stored near the surface, or by strict management practices.

A. Proposed Monitoring Requirements

The fundamental questions that were considered in developing the proposed compliance monitoring requirements are the following:

- How can monitoring regulations be developed to provide States with an active role such that resources are efficiently utilized?
- What minimum requirements should be set?
- What distinctions should be made between ground and surface water systems?

—What locations for sampling?
—Number of samples per system?
—One-time monitoring or monitoring over a period of time? Should minimum repeat frequency be established? What frequency and upon what basis?
—How must time should be allowed for public water systems to complete the monitoring requirements?
—What is the cost of monitoring per system?

- What sampling requirements should be set?
- What follow-up actions may be needed to assist the public water systems and the States when positives are reported?

—Follow-up confirmation sampling?
—Health and treatment advisories?

- What reporting and public notice requirements should be set?

Public comments are requested on each question above as they relate to the proposed requirements discussed below and the other alternatives presented.

EPA believes that all systems should conduct at least one initial round of monitoring to determine the extent of contamination of water supplies and to provide maximum consumer knowledge of the quality of their drinking water. EPA also believes that there should be minimum requirements for repeat sampling since the vulnerability of a system to VOC contamination may change with changing land and water use and waste disposal practices. The repeat sampling requirements should reflect the potential for contamination of the system (i.e., the most vulnerable systems should monitor the most frequently). The States should recertify the vulnerability status of each system on an annual basis. Systems should notify the State whenever a significant change takes place that could affect the vulnerability of the system (e.g., change in water source, new VOC-based industry nearby or a positive VOC analysis).

Several approaches to monitoring requirements have been considered by EPA. Three specific options are outlined below with additional details provided in Appendix B. Appendix B contains Table B–1 a detailed description of the monitoring options considered; further explanation is provided in the analytical methods/monitoring document. In each option, requirements are displayed for: (1) An initial round of monitoring and (2) repeat monitoring. In addition, different requirements are set within each option for ground water systems (about 45,000) and surface water systems (about 15,000). These requirements would also apply to those water systems previously considered non-community systems such as schools and factories. The primary differences between the options relate to the extent of specific sampling requirements and the opportunity for State discretion. In each option, monitoring for vinyl chloride would not be required for all systems. Ground water systems would be required to analyze for vinyl chloride only when other chlorinated 2-carbon VOCs (trichloroethylene, tetrachloroethylene, 1,2-dichloroethane, 1,1,1-trichloroethane, and 1,1-dichloroethylene) had been

detected; this is because EPA has concluded that the most likely explanation for vinyl chloride detection in ground waters is from *in situ* transformation; no requirements would be set for vinyl chloride monitoring in surface water systems because vinyl chloride is not expected to be found due to its high volatility.

In each option, monitoring requirements are proposed to be phased in depending upon the size of the systems. Phasing in requirements over four or five years allows public water systems laboratories and States sufficient time to efficiently allocate the necessary resources to conduct the monitoring and analysis. Systems that are most vulnerable to VOC contamination should sample first; while EPA studies have not shown a clear distinction between potential sources of contamination and actual VOC contamination that could be used to pinpoint specific systems that would be vulnerable to VOC contamination, the GWSS found the best correlation was between the size of systems and VOC contamination. In general, this could be expected since large population centers are located in areas of large commercial or industrial activity (users and producers of VOCs). However, smaller systems have also detected contamination by VOCs. Therefore, monitoring requirements are proposed to be phased in by system size with the largest systems sampling first.

EPA has also gathered occurrence data from several State surveys. These data are generally consistent with nationally based occurrence information in the GWSS. Although no additional projection can be made from these State surveys, they provide additional support for the initial monitoring requirements in this proposal. The regional surveys also provides such support; specifically, these data support the decision to phase in the monitoring requirements for VOCs based on population since frequency of VOC occurrence generally increases with increasing population served by the community water systems. These data also support the decision that all systems be required to monitor for VOCs since small and large systems have detected VOCs at relatively high concentrations, without apparent sources of contamination.

EPA is proposing that Option 2 be selected as the minimum federally enforceable monitoring requirements (Option 2 is described in Appendix Table B–1). Option 2 provides for reasonable minimum federal requirements and also provides for State discretion in their application. While the requirements are phased in by size of system, States are encouraged to sample vulnerable systems as early as possible. EPA requests comments on these three options; final monitoring requirements may be modified based on public comments.

1. *Option 1.* This option would require all systems to monitor at least once over a four year period. The federally mandated monitoring requirements would be relatively stringent under this option. The monitoring requirements would be phased-in based on the size of the population served by the system, as follows:

System size	Completed by
>10,000	End of 1 year.
3,300 to 10,000	End of 2 years.
<3,300	End of 4 years.

- Ground water systems would be required to sample at entry points to the distribution system. The minimum number of samples would be one sample per entry point to the distribution system per quarter and confirmation samples would be required.
- Surface water systems would be required to sample in the distribution system. The minimum number of samples would be one sample per source per month and confirmation samples would be required.

Ground and surface water systems would sample at least quarterly or monthly, respectively, for one year and would be required to resample any positive result. Sample locations for ground water systems are at entry points to the distribution system in order that contamination of any single well could be detected. Sampling in the distribution system might not detect contamination due to factors such as sample location and pumping patterns. It is thought that representative samples can be obtained within the distribution system for surface waters since there are usually fewer entry points.

Repeat monitoring would be based on prior monitoring results and the vulnerability of the system to VOC contamination. The repeat monitoring frequency would be as follows:

Status	Frequency
VOCs not detected in any one sample and not vulnerable.	Repeat in 5 years.[1]
VOCs not detected in any one sample and vulnerable.	Repeat in 3 years.[2]
VOCs detected	Monthly.

[1] States would annually recertify the vulnerability status of systems. Vulnerability criteria are discussed in Appendix A of this notice.
[2] Surface water systems sample during four consecutive quarters.

The estimated costs of this option at $150 per sample are as follows:

Initial round, $25 million/year (average) for 4 years

Repeat monitoring, $64 million/year

2. *Option 2.* The federally mandated monitoring requirements would be less stringent under this option than in Option 1. Like Option 1, all systems would monitor at least once over a four year period but fewer samples would be required than in Option 1. The monitoring program would be the same as in Option 1, phased-in based on the size of the population served by the system, i.e.:

System size	Completed by
>10,000	End of 1 year.
3,300 to 10,000	End of 2 years.
<3,300	End of 4 years.

- Ground water systems would be required to sample at entry points to the distribution system. The minimum of samples for ground water systems would be one sample per entry point to the distribution system, per quarter for one year. However, if a system was not considered vulnerable to contamination and the first quarterly sample did not detect VOCs, States would have discretion to reduce the sampling requirements to that one sample. In other words, that one sample in that quarter would complete monitoring for that year (and the next 5 years).
- Surface water systems would sample at points representative of each source. The minimum number of samples would be one sample per source, per quarter for one year.

States would have discretion on requiring confirmation samples for positive results.

All systems would be required to conduct repeat monitoring except for surface water systems that were not vulnerable and did not detect any VOCs in the first round of sampling. The frequency of such monitoring would be based on prior monitoring results and the vulnerability of the system to VOC contamination. The monitoring frequency would be as follows:

Status[1]	Ground water	Surface water[2]
VOCs not detected and not vulnerable.	Repeat in 5 years.	State discretion.
VOCs not detected and vulnerable.	Repeat in 3 years.	Repeat in 3 years.[2]
VOCs detected	Quarterly	Quarterly.

[1] States would annually recertify the vulnerability status of systems.
[2] Surface water systems sampled during four consecutive quarters.

States could reduce the repeat monitoring requirements for systems detecting VOCs but at levels less than the MCL from quarterly sampling to no less than yearly sampling after a baseline of data is developed. A minimum of three years of quarterly sampling is considered an adequate time span for gathering these data.

The estimated costs of this option of $150 per sample are as follows:

Initial round, $9.3 million/year (average) over 4 years

Repeat monitoring, $17 million/year

3. *Option 3.* More State discretion is provided under this option than the previous options. All ground water systems would monitor at least once over a five year period. Monitoring of surface water systems would be at State discretion based upon vulnerability. The monitoring program would be phased-in based on the size of the population served by the system as described in the previous options except that systems serving less than 500 people would have five years from the date of promulgation to complete the initial montioring, i.e.:

Size of system	Complete by
>10,000	End of 1 year.
3,300 to 10,000	End of 2 years.
500 to 3,300	End of 4 years.
>500	End of 5 years.

Ground water systems would be required to sample at entry points to the distribution system at points representative of each well at least once during the initial monitoring period. States would have discretion on requiring confirmation samples. Specific requirements for surface water systems would be up to State discretion based upon a vulnerability assessment. Repeat compliance monitoring requirements would only be for those systems that detected VOCs in the initial monitoring round. States would have discretion in the frequency of monitoring for those systems where VOCs were not found. The monitoring frequency would be as follows:

Status[1]	Ground water	Surface water
VOCs not detected and not vulnerable.	State discretion.	State discretion.
VOCs not detected and vulnerable.	State discretion.	State discretion.
VOCs detected	Annually	State discretion.

[1] States would annually recertify the vulnerability status of systems.

The estimated costs of this option at $150 per sample are as follows:

Initial round, $3.8 million/year (average) over 5 years

Repeat monitoring, $2.9 million/year

4. *Selection of Monitoring Requirements.* EPA is proposing Option 2. The phase-in period is shorter than Option 3, as EPA believes that such monitoring should begin and be completed as quickly as feasible given laboratory capacity. Given the variability of VOCs and their long-term risks, quarterly monitoring is deemed to be frequent enough to provide a reasonable representation of contamination and provide adequate health protection. The monitoring requirements are thought to be economically feasible. As an example, a system of 25 people with one well would have annual costs of $600 or $2 per month per person. Large system costs per person would be less. The monitoring frequency includes sampling for four consecutive quarters during the monitoring period for surface water systems since variability of surface waters is expected to be influenced more by seasonal and weather conditions. Ground water systems would be required to take four quarterly samples unless the first sample did not detect VOCs and the system was not considered vulnerable; in these cases States could waive the additional three samples. States have the option to reduce the repeat monitoring requirements for vulnerable systems that have detected VOCs at levels less than the MCLs to no less frequent than once a year after a baseline of data is developed. EPA expects that the States will have a major role in implementing these monitoring requirements. Assessments of vulnerability, extent of contamination, and individual system factors will determine the amount of monitoring properly conducted at each system. General guidance on the determination of vulnerability of systems is provided in Appendix A.

B. Determination of Compliance with MCLs

All compliance samples shall be collected on the same day and analyzed according to EPA approved procedures. Compliance with the MCL shall be computed by arithmetically averaging the quarterly values for each sampling point at the end of one year for each source of water. If the average for any source is above the MCL, that system shall be considered out of compliance. This approach is proposed because of the large variations of raw and finished water quality that may occur in a year. In addition, ground water or surface water systems with multiple sources and treatment plants could serve some consumers high levels of VOCs in a portion of the system over a period of many years. Determination of compliance by averaging the results from various sampling points across the system could mask the higher exposure of these consumers.

C. Public Comments

Public comments are requested on the proposed monitoring requirements and specifically on each of the fundamental questions that address monitoring listed previously. In addition:

- Are the proposed requirements affordable by public water systems, especially small systems?
- Are the frequencies proposed adequate to measure variability of VOCs in the drinking water?
- Is the active role of the States in the proposal a reasonable expection?
- The proposal for determination of compliance would provide that parts of a system could be out of compliance (and public notice required). This is a distinct change from the Interim Regulations which measured compliance for the entire public water system. Is this approach reasonable to provide maximum protection of the consumers?

VI. Monitoring for Unregulated Contaminants

This section addresses other VOCs for which MCLs and compliance monitoring requirements have not been proposed. Monitoring requirements are being proposed in this notice for these other, "unregulated" VOCs. The discussion below provides background information, describes statutory authority, and explains the proposed requirements.

A. Summary Statement of the Problem

Contamination of drinking water by organic pollutants is recognized as a serious problem across the country. Contamination has been detected through limited federal, State and local monitoring actions. Only a small percentage of systems have actually sampled their water to assess water quality for organic contaminants. Monitoring is currently not being conducted in a comprehensive manner by public water systems which would serve to alert the public to potential health risks in their drinking water and the need for remedial action. Results of compliance monitoring for drinking water standards would provide additional information but implementation of these standards are several years away and will not cover all possible contaminants in drinking water. Moreover, monitoring is necessary to identify additional contaminants which may require

National Primary Drinking Water Regulations.

B. Statutory Authority

The establishment of monitoring regulations is authorized by section 1445(a) of the SDWA which states:

> Every person who is a supplier of water, . . . shall establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation to assist him in establishing regulations, . . . in evaluating the health risks of unregulated contaminants or in advising the public of such risks.

C. Background

In recent years, numerous organic chemical contaminants have been found in drinking water including volatile synthetic organic chemicals, pesticides, disinfection by-products and other synthetic organic chemicals.

Assessment of the quality of drinking water in the U.S. has been accomplished through various monitoring activities including: (1) Compliance monitoring for the drinking water standards, (2) EPA conducted national statistically designed surveys of selected drinking water supplies, (3) State surveys, (4), responses to contamination, and (5) research studies.

These monitoring activities have been partially successful in determining the quality of the nation's drinking water:

• Widespread contamination potential of public water supplies has been determined to exist through these monitoring efforts. For example:

—About 20 percent of public water systems detected at least a trace of VOCs in the 1000 city ground water survey.

—Sampling of ground waters around hazardous waste sites has identified many synthetic organic chemicals (SOCs) that threaten public water supplies.

—Pesticides in ground and surface waters are the most recent concern as various pesticides have been detected in water supplies across the country; e.g., aldicarb, dibromochloropropane (DBCP), ethylene dibromide (EDB), and alachlor.

However, most small (and many large) public water systems are unaware of possible contamination of their supplies. Except for certain large systems and those in aggressive States, public water systems are not taking initiatives in monitoring for organics in their drinking water. Besides the chemicals that are known, it seems that every few months a new chemical is detected in drinking water that draws much public attention resulting in a wide variety of responses.

What appears to be needed is a systematic and comprehensive monitoring program that would determine the quality of drinking water in public water systems across the country. This would enhance public awareness of drinking water quality, encourage control actions (when appropriate, before standards could be implemented) and provide the basis for standard setting for additional contaminants.

Major interest in a monitoring program is being shown by Congress in legislation that would require monitoring for unregulated organic chemicals. Congressional debate has focused on the need for more occurrence data for standard setting and for widespread monitoring of unregulated contaminants. The intent of the monitoring requirements discussed by the Congress was: (1) Elevate public awareness regarding the quality of their drinking water, (2) identify problems of gross contamination for immediate remedial action by State and local authorities, and (3) identify additional contaminants for regulation. In Congress' view, requiring monitoring would stimulate interm measures for public health protection until drinking water regulations could be promulgated.

Given the apparent need for a monitoring program, EPA sponsored a public workshop in November 1984, to discuss the need for and specific aspects of possible monitoring regulations for unregulated contaminants in drinking water. Representatives of States, utilities, public interest groups, analytical laboratories and consultants attend the workshop. The universe of organic chemicals considered potential drinking water contaminants was split into two groups for evaluation by the workshop participants:

(a) *VOCs.* Available analytical procedures with modifications can measure up to 50 to 60 VOCs at a cost of about $150 to $200 per sample. Depending upon laboratory capabilities (e.g., GC vs. GC/MS) and other requirements such as quality assurance (QA) and confirmation of positives, costs could range up to a maximum of $400 to $500 per sample for 50 to 60 VOCs. The analytical capabilities of laboratories have improved over the last few years and laboratories are generally more aware of QA aspects of trace contaminant analyses. Most public water systems serving over 10,000 people are already monitoring for trihalomethanes (TTHMs) using similar analytical procedures.

(b) *Pesticides and other higher molecular weight SOCs.* While some pesticides/SOCs can be measured together, separate analytical techniques are generally required for analysis of pesticides and SOCs. Presently, analytical methodologies and laboratory capabilities are very limited for widespread use. Costs would be in the range of $1500 to $2000 per sample.

Workshop participants also carefully reviewed the recent experience in California in which the State legislature enacted legislation requiring monitoring for a large number of VOCs, SOCs and pesticides by public water systems serving greater than 200 service connections. Serious problems have been found in analytical methodology and laboratory capability for many of the pesticides and SOCs required for analysis.

Workshop participants concluded that EPA should develop regulations for monitoring for unregulated contaminants. General recommendations are provided below: (specific recommendations of the workshop are provided in Table 13).

• EPA should initially proceed with development of monitoring regulations for 40 to 50 VOCs at all public water systems.

• Before regulations are set for pesticides and SOCs, EPA should develop additional analytical capabilities, background occurrence and information or vulnerability of systems. Participants felt that because of the expense of monitoring, EPA should develop monitoring regulations such that they apply only to areas vulnerable to pesticide/SOC contamination. The National Pesticide Survey, now in planning, would assist in providing some of this data.

• The workshop did recommend, however, that monitoring could be initiated right away for a limited number of pesticides for which sufficient information is available.

Table 13.—Recommendations of Monitoring Workshop

VOCs

• Require monitoring by all community systems for at least 50 VOCs.

• Sample each well or surface water source in distribution system.

• Repeat monitoring every 3 years for all systems.

—Repeat annually for positives above an action level.

—State can modify based upon vulnerability assessment.

• Positive results: confirm by follow-up sample.

• Report to public all confirmed results. Report all results to State and EPA.

• Provide Health Advisories to enable public to understand the potential health risks.

SOCs/Pesticides

• Conduct national survey prior to development of monitoring regulations

—Costs of all systems to do all SOCs/Pesticides prohibitive ($1500 to $2000 per sample)

—Sensible approach: directed monitoring for those SOCs/Pesticides most likely to be present

—Survey should be conducted to collect data on occurrence and vulnerability to contamination

Alternate Approach to SOCs/Pesticides

• Set monitoring regulations where States have great flexibility to design program

• Require a number of screening tests (4 to 6) and evaluate unidentified peaks

• States can add/delete chemicals from list based on previous monitoring experience, usage and production patterns

• One sample per system (composites from different wells-OK)

• Phase in over 4 years

• Surface water systems: quarterly for 1 year. Composite sample for seasonal variations

• Sufficient laboratory capability exists

• Confirmed positives along with Health Advisories should be reported to the public in press releases or reports. Not in water bills.

The National Drinking Water Advisory Council (NDWAC) considered this issue in its December 1984 meeting and recommended that a systematic national monitoring program for unregulated VOCs and pesticides/SOCs be implemented. The NDWAC emphasized the need for VOC monitoring and monitoring for a limited number of pesticides for which sufficient analytical capabilities exist. Monitoring regulations for other pesticides/SOCs would follow as analytical methods and occurrence and health data become available.

D. Summary of Proposal

Because similar analytical procedures for the nine VOCs can also measure numerous other VOCs at relative small additional costs, monitoring regulations are being proposed for other VOCs in this notice. Monitoring for most pesticides and other SOCs is more costly and additional time is needed to develop analytical methods and baseline occurrence data (i.e., which pesticides should be monitoring for and in what locations) such that directed monitoring requirements can be developed (i.e., only those systems vulnerable to contamination would be required to monitor). The National Pesticides Survey will provide much of this preliminary data.

1. Selection of Contaminants

Two approaches have been considered in the selection of specific VOCs to be included in a monitoring regulation. The first and most comprehensive approach is to include all VOCs that can be detected (without complicating analytical problems) using the purge and trap gas chromatography techniques described in Section III of this proposal. Table 14 provides a list of the VOCs that can potentially be included as part of this proposal. The second approach considered is to include only those VOCs which have been detected in drinking water supplies to date and which have known and potential adverse health effects of human exposure. EPA believes that the monitoring efforts should include all chemicals: (1) That have been detected or are likely to occur in drinking water, (2) that have not been ruled out as posing no adverse health risk, and (3) that can be measured with little additional analytical effort. EPA is proposing that the VOCs listed in Table 14 be included in monitoring requirements as part of this proposal. The compounds included are:

• Four trihalomethanes (identified in the November 29, 1979 **Federal Register** and regulated in CWS serving more than 10,000 persons);

• Additional VOCs being considered for later phases of the Revised Regulations;

• VOCs not included above but detected in the Ground Water Supply Survey and various federal and State surveys.

• Other VOCs based upon their potential for occurrence in drinking water: VOCs detected in waste waters, surface or ground waters or have widespread dispersive use patterns and high production; and

• Other VOCs based upon ease of analytical determinations. The VOCs in Table 14 can be measured in a single analysis by GC/MS or by two separate analyses using GC. Estimated costs are $150 to $200 for the GC/MS, and for the two GC analyses $100 per GC analysis is a useful rule for estimating costs. Some cost savings are expected by laboratories if detectors are used in series, thus requiring only one GC analysis. The two analyses include:

• Purgeable halogenated hydrocarbons

• Purgeable aromatics

The analysis of highly volatile substances can be accomplished using the procedures for the purgeable hydrocarbons through minor adaptations (e.g., change the trapping device).

EPA requests comments on the specific contaminants listed in Table 14 and whether additional contaminants besides the 51 in this proposal should also be included, such as synthetic organic chemicals or pesticides. Development of Health Advisories for each of the VOCs is planned to coincide with the implementation of the monitoring requirements. Health Advisories are non-regulatory guidance on the health risks of exposure to contaminants in drinking water for various durations of exposure.

Monitoring for EDB and DBCP (compounds requiring low limits of detection) requires special analysis estimated to cost an additional $50 per sample. Monitoring for EDB and DBCP will only be required for systems considered to be vulnerable to EDB or DBCP contamination. Procedures are currently being used by EPA, State and contract laboratories to nominally analyze for EDB and DBCP to 20 ng/l. These procedures are based on co-distillation or liquid-liquid extraction followed by GC analysis using electron capture detection. A draft method now available for EDB and DBCP analyses is Method 504, Measurement of 1,2-Dibromomethane (EBD) and 1,2-Dibromo-3-chloropropane (DBCP) in Drinking Water by Microextraction and Gas Chromatography, August 1985, available from the Envrionmental Monitoring and Support Laboratory, U.S. EPA, Cincinnati, Ohio 45268. Public comments are requested on the availability and adequacy of procedures for routine monitoring for EDB and DBCP. Also, public comments on analytical costs and precision and accuracy of analysis at these levels are requested.

Table 14.—VOCs Proposed in Monitoring Regulations for Unregulated VOCs

Chloroform
Bromodichloromethane
Chlorodibromomethane
Bromoform
trans-1,2-Dichloroethylene
Chlorobenzene
m-Dichlorobenzene
Dichloromethane

cis-1,2-Dichloroethylene
o-Dichlorobenzene
1,2,4-Trichlorobenzene
Fluorotrichloromethane
Dichlorodifluoromethane
Dibromomethane
1,2-Dibromoethane (EDB)
1,2-Dibromo-3-chloropropane (DBCP)
Toluene
p-Xylene
o-Xylene
m-Xylene
1,1-Dichloroethane
1,2-Dichloropropane
1,1,2,2-Tetrachloroethane
Ethylbenzene
1,3-Dichloropropane
Styrene
Chloromethane
Bromomethane
Bromochloromethane
1,2,3-Trichloropropane
1,2,3-Trichlorobenzene
n-Propylbenzene
1,1,1,2-Tetrachloroethane
Chloroethane
1,1,2-Trichloroethane
Pentachloroethane
bis-2-Chloroisopropyl ether
sec-Dichloropropane
1,2,4-Trimethylbenzene
n-Butylbenzene
Naphthalene
hexachlorobutadiene
o-Chlorotoluene
p-Chlorotoluene
1,3,5-Trimethylbenzene
p-Isopropyltoluene
1,1-Dichloropropane
iso-Propylbenzene
tert-Butylbenzene
sec-Butylbenzene
Bromobenzene

Analysis for unregulated contaminants must be conducted in laboratories certified by the State. Because the monitoring for unregulated contaminants will be required before full certification programs can be implemented, interim certification will be provided to those laboratories that are: (1) Presently certified for trihalomethane analyses and, (2) able to analyze performance evaluation samples for additional VOCs within acceptable limits (±20%, ±40%).

2. Proposed Monitoring Requirements for Unregulated VOCs

Three options for the establishment of minimum monitoring requirements were considered for unregulated VOCs. These options are similar to those described for VOC compliance monitoring (Section IV of this proposal). The options range from an extensive federally mandated specific monitoring program to monitoring program whose specifics (e.g., repeat monitoring frequencies) would be largely determined by the States. The second option below is being proposed because EPA considers that such a monitoring program provides reasonable minimum federal requirements and allows for State discretion in their application. Of course, systems need not monitor for unregulated contaminants as frequently.

Insofar as possible, the monitoring requirements for unregulated VOCs will be similar to those proposed for compliance monitoring under the NPDWR so that systems will be allowed to use the same samples for analysis of both the VOCs in Table 14 and the VOCs for which MCLs are proposed. In addition provisions for "grandfathering" previous data for acceptable quality are included. The three options for minimum federally mandated monitoring requirements outlined below generally correspond to the three options described earlier for compliance monitoring for the VOCs in this proposal. Appendix B provides additional details on each of the options.

a. *Option 1.* This option proposes relatively stringent monitoring requirements and includes minimum repeat monitoring for all systems. The monitoring program would be phased-in over a four year period based on the size of the population served by the water system in a similar manner as described under Option 1 of the proposed compliance monitoring requirements. Ground water systems would be required to sample once at the well head. Surface water systems would be required to sample quarterly for one year in the distribution system at points representative of each source. All systems would be required to resample positive samples. All systems would be required to repeat monitoring every 10 years.

b. *Option 2.* This option is the same as Option 1 above except that it provides for State discretion on resampling positive results; repeat monitoring requirements would not be required but woud be at State discretion.

c. *Option 3.* Under this option all systems would monitor once over a five-year period. Monitoring would be phased-in by the size of population served by the water system as described under Option 3 of the compliance monitoring requirements. Ground water systems would be required to randomly sample only 25 percent of their wells and the sampling would be done at the well head. The State would have discretion on whether to require confirmation samples. Also, States would have discretion on whether to require surface water systems to monitor based upon a vulnerability assessment. There is no repeat monitoring requirement under this option.

Estimated additional monitoring costs for the three options are shown in Table 15. These costs are based on the assumption that water supply systems will opt to monitor for compliance with MCLs and for unregulated VOCs simultaneously. Details are presented in the Methods/Monitoring Document referenced in Section IX.

TABLE 15.—COSTS FOR MONITORING OF UNREGULATED VOCS

[In millions of dollars]

	Option 1	Option 2 [1]	Option 3 [2]
Initial Round	$2.7	$2.3	$0.5
Repeat Monitoring	2.7	0	0

[1] Over 4 years.
[2] Over 5 years.

d. *Selection of Monitoring Requirements.* Option 2 is being proposed and Table 16 summarizes the proposed monitoring requirements. As discussed above, one sample for every well is felt to be needed to collect representative data; geologic conditions, pumping patterns, and other factors are known to result in variations between wells in the same well field (e.g., certain wells are contaminated but another close by well is not). The variability in concentration levels is also known to vary but it is felt that one sample should determine if the well is contaminated by VOCs; the levels may vary but the VOC analysis will detect if VOCs are present. Confirmatory analyses and follow-up actions by the State would be expected to determine the more precise nature of the contamination.

TABLE 16.—PROPOSED MONITORING REQUIREMENTS FOR UNREGULATED VOCS

Initial Monitoring
- All systems monitor once over four years
- Requirements are by system size:

Size of System	Complete by End of
>10,000	1 year.
3,300 to 10,000	2 years.
<3,300	4 years.

- Ground Water Systems: One sample entry point to distribution system.
- Surface Water Systems: Quarterly samples per each source for one year at points in distribution system representative of each source.

Repeat Monitoring
- State discretion for repeat sampling; dependent upon vulnerability and results of first round of monitoring.

EPA is proposing to implement this option through a new regulation to be codified at 40 CFR 141.40. EPA would delete existing § 141.40, "Special monitoring for organic chemicals". This regulation was adopted in 1975 to allow

the Agency to require designated systems to conduct monitoring for specified organic chemicals. Because the new regulation provides a comprehensive scheme for monitoring for VOCs, old § 141.40 will be deleted. EPA intends to propose more monitoring requirements for other organic and inorganic contaminants which will appear as a subsection to § 141.40 or as a new section in Subpart E of Part 141.

States are expected to play a major role in implementation of these monitoring requirements especially in activities following the first round of sampling. Depending upon the vulnerability of systems and results of the first sampling, States are encouraged to require confirmation of contamination and assist in remedial measures for removal of these contaminants from drinking water.

Public comments are requested on the need for monitoring for unregulated contaminants and on specific aspects of the proposed requirements. For example, public comments are specifically requested on if repeat monitoring requirements should be set at every 10 years or some other period or if State discretion is sufficient for repeat monitoring.

VII. Reporting Requirements

The Interim Regulations currently require public water systems to report monitoring data to States within specified time periods. No changes are being proposed in those requirements for the Revised Regulations. Public comments are requested on those requirements and whether they should be changed.

For monitoring unregulated VOCs, requirements are proposed such that public water systems will report the analytical results of the unregulated contaminants to either: (a) The State, if the State has adopted the monitoring requirements for the unregulated contaminants, equivalent to those required by the federal regulations, or (b) to EPA if the State has not adopted equivalent monitoring requirements. Any State which adopts equivalent monitoring requirements will be asked to submit all of the information to EPA so that EPA can compile a nationwide file on the occurrences and levels of these unregulated contaminants. EPA intends to use the analytical results to evaluate the health risks of the contaminants and believes it is necessary to have all available results.

The data collection approach proposed here is believed to be the most reasonable one available as it is the least burdensome on the water systems. It assumes, however, that States which have adopted monitoring requirements for the unregulated contaminants will provide all of the collected analytical results to EPA.

An option to this proposal in order to insure that EPA receives all such analyses, is to establish regulations to require system to submit these monitoring results to EPA regardless of whether the State has adopted the equivalent regulations. Water systems in a State which had adopted monitoring requirements for unregulated contaminants could thus be required to submit such results twice: once to the State and once to EPA. Public comments are requested on these two options.

VIII. Public Notice Requirements

Current regulations at 40 CFR 141.32 require that any violation of a maximum contaminant level, failure to comply with an applicable monitoring provision, or failure to comply with any monitoring required pursuant to section 1445(a) of the Act be reported to the persons served by the water system. No change to those requirements are being proposed for the VOCs. The regulations are very specific in when, where, and who, and how the public notification is to be made. These requirements were based upon very specific directions in the SDWA, Section 1414. Some problems with effective notification have been experienced primarily because of the specificity of the requirements. Added flexibility appears to be needed and is currently under consideration in reauthorization of the SDWA. If the SDWA is amended in the area of public notification, the regulations would be modified as appropriate.

Section 1413 provides authority for EPA to require public notification of the results of monitoring for unregulated contaminants. It also gives the Agency the authority to prescribe the form and content of the public notification. Under this section and sections 1445(a) and 1450(a), EPA has the authority to direct to whom monitoring results should be sent.

Regulations are proposed today (proposed § 141.34) for unregulated VOCs and include a provision which would require the supplier to notify his/her consumers of the availability of the analytical results of the unregulated contaminant monitoring. The proposed regulations would also require the supplier to submit a representative copy of each public notification to either the State (if it has adopted the monitoring requirements for the unregulated contaminants), or EPA (if the State has not adopted equivalent monitoring requirements). These requirements would meet the SDWA objective of providing information on drinking water contamination to consumers of that water. Public comment is requested on the following:

- Should the notification tell the users that monitoring was conducted and that the results are available to interested parties?
- Should the notification give specific detail on the contaminants monitored, the results and the anticipated health significance of the presence of the contaminants?
- Who should be notified of the monitoring program and the analytical results, and how should the notification, be conducted (i.e., newspaper or media notification, written notice with water bill)?
- How much time should elapse between the supplier's receipt of the analytical results and the notification of the users that the results are available?
- How frequently should the notification occur?

IX. Economic Impact Assessment

An impact assessment has been prepared and is entitled "Economic Impact Analysis of Proposed Regulations to Control Volatile Synthetic Organic Chemicals (VOCs) in Drinking Water" (see section X). The assessment was prepared in response to Executive Order (E.O.) No. 12291 which requires the Agency to consider costs and benefits for all regulations. It was determined that this regulation was not a major regulation, that a Regulatory Impact Analysis was not needed, and that only an economic impact analysis was needed. The analyses in the report are based on the documents prepared by the Agency which present information on health effects, contamination occurrence, the cost and technology of contaminant removal and analytical methods. As required by E.O. 12291, this information was evaluated to permit estimation of the benefits and costs of regulatory alternatives. Also included are analyses required by the Regulatory Flexibility Act and the Paperwork Reduction Act.

E.O. 12291 does not distinguish between the legislative authority of various statutes but requires the same kinds of information in each analysis. Therefore as a result, some of the information and analyses presented in the analysis have been conducted to meet the specific requirements of E.O. 12291 regarding cost/benefit analysis and were not used in determination of the MCLs. The SDWA requires setting MCLs with use of best generally available technology (taking costs into

consideration); according to legislative history, costs are to be determined by what is reasonably affordable for large metropolitan water systems. However, in many instances, drinking water regulations will provide net benefits, despite the fact that the MCLs are not required to be set using a cost-benefit approach. Information on costs and benefits required by E.O. 12291 is useful to EPA and the public in estimating the impact of the drinking water regulations. The data presented below summarize the impact assessment.

A. Alternatives Examined

The impact assessment examines several regulatory alternatives. Those presented in this notice reflect the viable alternatives which received serious consideration throughout the decision-making process. The MCL alternatives evaluated reflect drinking water concentrations of 1, 5 and 10 μg/l for each of the potential carcinogenic contaminants. While none of these alternatives is identical to the proposed rule, the 5 μg/l alternative is considered essentially the same. The analysis presents further data on alternatives from 0.5 μg/l to 100 μg/l, and also includes alternatives based on risk rather than feasibility.

B. Economic Impacts

Table 17 presents the economic impacts associated with three alternatives. Approximately 1,300 community water supplies would be expected to exceed the proposed standards. If nearly all these systems took action to comply with the proposed regulations, the total cost to the nation for treatment would be about $280 million. On an annual basis the cost of treatment would be about $21 million per year. As presented in Table 17, the "total social cost" is the present year value-constant dollar cost of the proposals over a twenty year period and includes both capital and annual costs. Imbedded in these estimates are the assumptions that capital costs are all incurred in the first year, and an inflation free discount rate of 4.4 percent (applied to annual operation and maintenance costs).

The "annualized costs" is a constant dollar estimate of the capital cost (amortized at 4.4%) plus the annual operation and maintenance costs. These costs are also inflation free.

The cost impacts on water systems and consumers affected by volatile organic contamination vary depending upon the size of the utility. Very small systems which serve from 25 to 500 people could be expected to increase their water rates by less than 60 cents per 1,000 gallons of water. As a result of economies of scale, large systems serving more than 50,000 people could be expected to increase their rates only about 2 cents per thousand gallons. These increases would only affect systems with contaminant levels above the proposed standard.

A typical family served by a very small water system could expect to spend about $91 more each year in order to receive safer drinking water. A family living in a large community would pay only about $3 more each year. Again, these costs would only affect families receiving water that is not contaminated at levels above the proposed standard.

Examination of Table 17, and the Economic Impact Assessment, shows that the cost to the system or the family is not significantly different for the various regulatory alternatives. If a system does take action to reduce volatile organic contamination in its drinking water, the basic cost of implementing a change in water treatment or supply is not very sensitive to the treatment removal efficiency. The reason the national costs vary is that with lower concentration alternatives there are more systems who would have to implement treatment. This analysis of national costs only reflects the economic impacts of selected MCL ranges and was not used to determine the MCLs.

The cost impacts on State governments are also presented in the assessment. While the cost to any particular State of managing the proposed regulations would depend on the number of systems in the State, the total cost to all States would be approximately $4 million in the first year and $2 million in each succeeding year. On average, this is less than $100,000 per State in the first year and less than $50,000 per State in the following years.

This notice also proposes a monitoring program which will be used to determine compliance with the regulation as well as examine whether other volatile organic contaminants are present. The cost of the compliance monitoring is shared by all water systems in the nation. For those which find at least one of the nine regulated chemicals additional follow-up monitoring will be required. In addition, all systems will look for unregulated volatile contaminants as well, but no follow-up monitoring will be required. The initial round of compliance monitoring will be phased in over a period of four years.

The total cost of the initial round will be about $9.3 million per year. The follow-up monitoring will cost about $19 million per year for the first few years. Monitoring for unregulated contaminants will be done simultaneously with the initial round of compliance monitoring and will cost about $2.3 million per year.

C. Benefits

The risk posed by certain volatile organic contaminants found in drinking water is, in the main, cancer; other chronic toxic effects are also posed. Drinking water standards will ensure that water systems react to contamination properly. It will require action on contaminated water systems and provide appropriate targets for clean-up of contaminated drinking water supplies. The impact assessment presents information on the level of benefits associated with the various alternatives as well as comparisons of the benefits and costs of each.

The proposed regulation is expected to reduce the amount of new cancer that might arise each year by about 32 cases in the worst case scenario. Much of this benefit (about 29 cases) is attributable to control of the potentially extremely potent carcinogen vinyl chloride. It should be remembered that vinyl chloride appears only to be found with other contaminants, and may result from the *in situ* biodegradation of some of them. Therefore, control of the risk posed by vinyl chloride may require control of the potential precursor contaminants, especially since significant benefits arise from control of vinyl chloride even when it is present only at very low levels. In the absence of standards for the other volatile contaminants, many of the benefits of vinyl chloride removal probably would not arise.

The Economic Impact Assessment devotes significant attention to the issue of costs of controlling volatile organic contaminants and the benefits of control. As one would expect, when only a few people are served by a contaminated system, the cost per case of disease avoided can be quite large. Table 17 presents the average cost per case of disease for each alternative regulation, broken out by system size. The cost per case for the proposed regulation varies from $200,000 to $5 million per case, depending on system size.

D. Uncertainty

Computations of the benefits or costs associated with a proposal are subject to error from many sources. The result depends on estimates of a number of contributing factors, each of which is imperfectly known to a greater or lesser degree. More importantly, some contribute significantly to uncertainty in

estimates while others are relatively unimportant. Risk calculations can vary over orders of magnitude depending upon which risk extrapolation model is used. As discussed in the June 12, 1984 proposal, while the uncertainties are large [i.e., orders of magnitude), risk models are the best available scientific means for estimating risk of human exposure. When computing benefits, if the uncertainties in the risk extrapolation calculation are not included, the uncertainty was found to be dominated by the errors in the exposure data; i.e., there is a 95 percent likelihood that the true value of the benefits of the proposed MCL is within the range of 10 to 60 cases per year.

In like measure a major contribution to the uncertainty in cost estimates is error in the occurrence data. However, other factors such as the probability of treatment selection also contribute significantly. Much like the benefits calculation computation of the national costs followed a specific mathematical equation. The Economic Impact Assessment describes both equations as well as the importance of each element on the resultant uncertainty. The resulting analysis suggests there is a 95 percent likelihood that the true value of annual national costs of the proposed MCL is within the range of $0 to $45 million.

E. Major Rules

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This proposed action does not constitute a "major" regulatory action because it will not have a major financial or adverse impact on the community. However, an Economic Impact Analysis was prepared during the regulation development and this regulation was submitted to the Office of Management and Budget for review.

F. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires EPA to explicitly consider the effect of proposed regulations on small entities. If there is a significant effect on a substantial number of small systems, means should be sought to minimize the effects.

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, I certify that this proposed rule will not have a significant effect on a substantial number of small entities. The Small Business Administration defines a small water utility as one which serves fewer than 50,000 people. There are about 58,500 systems which, for the purposes of this analysis, are considered small systems. Of course, this analysis under the Regulatory Flexibility Act is to portray the regulated community against other U.S. entities. In this regard, most public water systems are considered small. Of the 58,500 small systems fewer than 1,300 are likely to have contamination levels greater than the proposed MCL. This proposal would regulate less than 3 percent of the "small" systems and this does not constitute a substantial number of small systems. In addition, the cost impacts on systems will lead to increases in water rates of no more than 20 percent, and more typically less than 10 percent.

G. Paperwork Analysis

The Paperwork Reduction Act seeks to minimize the reporting burden on the regulated community as well minimize the cost of federal information collection and dissemination. The information collection proposed by this rule is of two types. Monitoring is proposed which will indicate if a water utility is in compliance with the proposed standard. There is no way to determine if a water is safe to drink without such monitoring.

The second type of information collected is monitoring data on contaminants which are not now regulated. This proposal would provide all of the people in the nation served by community water systems information on whether there are important chemical pollutants in their water. The importance of this monitoring is described in the section on monitoring for unregulated contaminants. The cost of the proposed monitoring is shown in Table 17.

TABLE 17.—SUMMARY OF IMPACTS OF THE REGULATORY OPTIONS

	Regulatory options		
	1 µg/l	5 µg/l	10 µg/l
Systems Impacted, National Cost of Control	3,800	1,300	800
Total social cost (dollar in millions):	$1,300	$280	$150
Annualized cost (dollar in millions)	100	21	11
National Cost of Monitoring:			
Compliance (dollar in millions/year-4 years)		$9.3	
Unregulated Contaminants (dollar in millions/year)		2.3	
Annual Cost per Family (dollar per year) System Size (people served):			
Very Small (25-500)	$96	$91	$90
Small (501-3,300)	47	41	42
Medium (3,301-50,000)	12	12	11
Large (over 50,000)	8	3	1
Typical Rate Increases (dollar per 1,000 gal):			
Very Small (25-500)	$0.58	$0.54	$0.58
Small (501-3,300)	0.33	0.29	0.29
Medium (3,301-50,000)	0.07	0.07	0.07
Large (over 50,000)	0.04	0.02	0.01
Annual Cancer Cases Avoided:			
Total	42	32	31
Attributable to Vinyl Chloride	37	29	27

TABLE 17.—SUMMARY OF IMPACTS OF THE REGULATORY OPTIONS—Continued

	Regulatory options		
	1 µg/l	5 µg/l	10 µg/l
Average Cost/Case Avoided (dollar in millions):			
Very Small (25-500)	$10	$5	$4
Small (501-3,300)	7	3	2
Medium (3,301-50,000)	2	0.6	0.4
Large (over 50,000)	2	0.2	0.04

X. Public Docket/References

Public comments, supporting documents and the index to the public docket are maintained at EPA in Room 2904 (rear). All other supporting materials pertinent to the development of this proposal are included in the public docket located at EPA headquarters, Washington, D.C. The public docket is available to the public and the public should contact the Drinking Water Regulations Docket Manager (Ms. Kitty Miller, 202/382-3022) for access. Materials in the public docket include such documents as the following:

- Public comments on the ANPRM and Proposed Rulemaking for RMCLs
- Transcript of public meetings
- Report and background material for the four public workshops, Summer 1982
- Transcripts and meetings of NDWAC meetings
- Summaries of meetings, telephone calls from outside EPA
- Letters to/from the public
- Technical reports
- Other supporting materials

The following supporting documentation for this proposal is available on request from the address (NTIS) listed at the beginning of this notice.

Environmental Science and Engineering. Technologies and Cost for the Removal of Volatile Organic Chemicals from Potable Water Supplies. May 1985.

EPA, Criteria and Standards Division. Analytical Methods/Monitoring for VOCs in Drinking Water. October 1985.

EPA, Summary of Available Information Related to the Occurrence of Vinyl Chloride in Ground Water as a Transformation Product of other Volatile Organic Chemicals. October 1985.

Other pertinent references available in the public docket include the following:

EPA, EMSL. "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography. Method 503.1". September 1984.

EPA, EMSL. "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatogoraphy/Mass Spectrometry. Method 524.1". May 1985.

EPA, EMSL. "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography. Method 502.1". September 1984.

EPA, Office of Program Development and Evaluation, Economic Impact Analysis of Proposed Regulations to Control Volatile Synthetic Organic Chemicals (VOCs) in Drinking Water. October 1985.

XI. Request for Public Comment

EPA requests public comments and relevant information on all aspects of the proposed regulations. The questions for which comment is being specifically solicited have been provided in the above discussion; several additional questions are listed below. Comment will be of great assistance to EPA in formulating a protective and practical approach to reducing human exposure to VOCs in drinking water.

- Do the MCLs represent a level "as close to the RMCL as feasible"?

—Is the methodology for determining the MCLs appropriate?

—Are the levels set for the MCLs feasible?

—Are the costs of meeting the MCLs reasonable?

- Should packed tower aeration and granular activated carbon be considered best available technologies for determination of the MCLs?

—Is it reasonable to assume up to 99 percent removal for packed tower aeration for the nine VOCs (up to 99.9% for vinyl chloride)?

—Are the costs of treatment sufficiently accurate? Do they reasonably represent what could be expected in real-world situations?

- Should point-of-use or point-of-entry GAC adsorption devices be considered as available technology suitable for meeting the proposed MCLs?

—Are the propsed criteria adequate for protection of public health?

—Can the utility and primary agency assure that point-of-use/entry treatment will afford protection equivalent to central treatment?

- Bottled water has been rejected as an acceptable means of meeting MCLs on a permanent basis. Is this reasonable under the SDWA?

- Is the approach to setting PQLs reasonable?

—Is the use of ±40% acceptance limits a useful and valid criterion to set PQLs for VOCs.

—In the absence of sufficient information/data on inter-laboratory studies, is the use of 5 to 10 times the MDL a reasonable approach to determine the PQL?

—Are PQLs of 5 μg/1 for eight of the VOCs and a PQL of 1 μg/1 for vinyl chloride reasonable?

- Are the monitoring costs ($150–$200/sample) representative of actual costs?

- Do the proposed compliance monitoring requirements serve the purpose of insuring that high quality water is available?

- Is the proposal for monitoring for unregulated VOCs reasonable? Should pesticides and other SOCs be included at this time? Should repeat monitoring be established at 10 year intervals or should repeat monitoring be left to State discretion?

- Is there any information to suggest that there is a significant occurrence of vinyl chloride in ground water that is not the result of *in situ* transformation?

A public meeting will be held for the interested public to comment and provide information and data on the proposed MCLs, compliance monitoring, reporting and public notice requirements and monitoring for unregulated VOCs. The date and location of the meeting are provided in the Dates section of this notice.

List of Subjects

40 CFR Part 141

Chemicals, Intergovernmental relations, Radiation protection, Reporting and record keeping requirements, Water supply.

40 CFR Part 142

Administrative practice and procedure, Chemicals, Radiation protection, Reporting and recordkeeping Requirements, Intergovernmental relations, and Water supply.

Dated: October 10, 1985.

Lee Thomas,

Administrator.

For the reasons set out in the preamble, Parts 141 and 142 of Title 40, Code of Federal Regulations is proposed to be amended as set forth below.

PART 141—[AMENDED]

1. The authority citation for Part 141 continues to read as follows:

Authority: 42 U.S.C. 300g–1, 300g–3, 300j–4, and 300j–9.

§ 141.2 [Amended]

2. In § 141.2, new paragraphs (v) and (w) are proposed to be added to read as follows:

* * * * *

(v) A point of use treatment device is a treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that one tap.

(w) A point of entry treatment device is a treatment device applied to the drinking water entering a house or building for the purpose of reducing contaminants in the drinking water distributed throughout the house or building.

3. It is proposed that a new paragraph (g) be added to § 141.24 to read as follows:

§ 141.24 Organic Chemicals Other than total trihalomethanes, sampling and analytical requirements.

* * * * *

(g) Analysis of the contaminants listed in § 141.61(a)(1)–(9) for purposes of determining compliance with the maximum contaminant levels shall be conducted as follows:

(1) Surface water systems shall sample at points in the distribution system representative of each source. The minimum number of samples is one sample every three months for one year per source. Sampling must be conducted at the same location or a more representative location each quarter.

(2) Ground water systems shall sample at points of entry to the system representative of each wells. Sampling must be conducted at the same location or a more representative location each quarter. The minimum number of samples is one sample every three months for one year per entry point to the distribution system. If VOCs listed in § 141.61(a) or in § 141.40(e) are not detected in the first sample and the system is not considered vulnerable, as defined in paragraph (g)(6)(iv) of this section the State may waive further sampling but may not waive the requirements of (g)(6) of this section.

(3) Systems that detect the VOCs listed in § 141.61(a)(1)–(8) or in § 141.40(e) following the procedures listed in paragraphs (g)(9) and (g)(10) of this section in any sample must commence monitoring following the requirements of paragraphs (g)(1) and (g) (2) of this section.

(4) All community water systems serving more than 10,000 people, shall analyze all distribution or entry-point samples, as appropriate representing all source waters within one year of the date of promulgation of this regulation. All community water systems serving from 3,300 to 10,000 people, shall analyze all distribution or entry-point samples as appropriate, representing source waters within two years of the date of promulgation of this regulation. All other community water systems shall analyze distribution or entry-point samples, as appropriate, representing all source waters within four years of the date of promulgation.

(5) The State may require confirmation samples for positive or

negative results, on written notice to the system by regulation.

(6) Analysis for vinyl chloride is required only of ground water systems that have detected one or more of the following VOCs: Trichloroethylene, tetrachloroethylene, 1, 2-dichloroethane, 1, 1, 1-trichloroethane, cis-1, 2-dichloroethylene, trans-1, 2-dichloroethylene, or 1, 1-dichloroethylene. Surface water systems may be required to analyze for vinyl chloride at the discretion of the State.

(7) All ground water systems and surface water systems shall conduct repeat monitoring.

(i) The repeat monitoring frequency for ground water systems is as follows:

VOCs not detected and system not vulnerable—Repeat in 5 years
VOCs not detected and system vulnerable—Repeat in 3 years
VOCs detected—Quarterly, as required under (g)(1) of this section

(ii) The repeat monitoring frequency for surface water systems is as follows:

VOCs not detected and not vulnerable—State discretion
VOCs not detected and vulnerable—Repeat in 3 years
VOCs detected—Quarterly, as required under (g)(2) of this section

Surface water supplies shall monitor four consecutive quarters during the monitoring period.

(iii) States may reduce to once per year the repeat monitoring requirements for systems detecting VOCs at levels consistently less than the MCL for three consecutive years.

(iv) Vulnerability shall be determined by the State based upon an assessment of the following factors:

(A) Previous monitoring results.

(B) Number of persons served by public water system.

(C) Proximity of a smaller system to a larger system.

(D) Proximity to commercial or industrial use of VOCs.

(E) Protection of the water source.

(v) A system is deemed to be vulnerable for a period of three years after any positive measurement of one or more VOCs listed in either § 141.61(a) or § 141.40(e) except for trihalomethanes or other demonstrated disinfection by-products.

(8) Compliance with § 141.61(a) shall be determined by arithmetically averaging the results of quarterly sampling over a one-year period for each sampling location. If one location's average is greater than the MCL then the system shall be deemed to be out of compliance.

(9) Analysis under this paragraph shall be conducted using EPA methods 502.1, "Volatile Halogenated Organic Chemicals in Water by Purge and Trap Gas Chromatography"; 503.1, "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography"; or 524.1, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry." These methods are contained in "Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water," June 1985, available from Environmental Monitoring and Support Laboratory (EMSL), EPA, Cincinnati, Ohio.

(10) Analysis under this section shall only be conducted by laboratories that have analyzed Performance Evaluation samples provided by EMSL to within ±40% of the reference value at concentrations below 100 μg/l and within ±20% of the reference value at concentrations at 100 μg/l and above.

(11) States have the authority to use monitoring data collected up to three years prior to the effective date of this regulation for purposes of determining compliance with the MCLs provided that requirements in this paragraph are met.

(12) States may increase monitoring where necessary to detect variations within the system.

(13) The State has the authority to determine compliance or initiate enforcement action based upon analytical results and other information compiled by their sanctioned representatives and agencies.

4. It is proposed that § 141.32 be amended by *revising the first clause of paragraph (a)* as follows:

§ 141.32 Public notification.

(a) If a community water system fails to comply with an applicable maximum contaminant level established in Subpart B or G, . . . * * *

* * * * *

5. It is proposed that a new § 141.34 be added to Subpart D of Part 141 to read as follows:

§ 141.34 Reporting and public notification for certain unregulated contaminants.

(a) The requirements of this section only apply to the contaminants listed in § 141.40.

(b) Public water systems required to monitor under § 141.40 shall send a copy of the results of such monitoring within 30 days of receipt and any public notice under paragraph (c) of this section to the State, if the State has adopted regulations equivalent to § 141.40 and this section or to EPA if such regulations have not been adopted.

(c) The supplier of water shall notify persons served by the system of the availability of the results by including a notice in the first set of water bills issued by the system after the receipt of the results, and in any event by written notice within three months. If the system issues water bills less frequently than quarterly, or does not issue water bills, the notice shall be made by or supplemented by another form of direct mail. The notice shall specify a person to contact for information on the monitoring results.

6. It is proposed that 40 CFR 141.40 be revised to read as follows:

§ 141.40 Special monitoring for organic chemicals.

(a) All community water systems shall monitor for the contaminants listed in paragraph (e) in this section as follows:

Number of persons served	Monitoring completion date
Over 10,000	Within 1 year of promulgation.
3,300 to 10,000	Within 2 years of promulgation.
Less than 3,300	Within 4 years of promulgation.

(b) Surface water systems shall sample in the distribution system at entry points representative of each water source. The minimum number of samples is four quarterly samples per water source.

(c) Ground water systems shall sample at points of entry to the distribution system representative of each well. The minimum number of samples is one sample per entry point to the distribution system.

(d) The State may require confirmation samples for positive or negative results by written notice to the system or by regulation.

(e) Community water systems shall monitor for the following contaminants except as provided in paragraph (f) of this section:

(1) Chloroform
(2) Bromodichloromethane
(3) Chlorodibromomethane
(4) Bromoform
(5) trans-1,2-Dichloroethylene
(6) Chlorobenzene
(6) m-Dichlorobenzene
(7) Dichloromethane
(8) cis-1,2-Dichloroethylene
(9) o-Dichlorobenzene
(10) 1,2,4-Trichlorobenzene
(11) Fluorotrichloromethane
(12) Dichlorodifluoromethane
(13) Dibromomethane
(14) 1,2-Dibromoethane (EDB)
(15) 1,2-Dibromo-3-chloropropane (DBCP)

(16) Toluene
(17) p-Xylene
(18) o-Xylene
(19) m-Xylene
(20) 1,1-Dichloroethane
(21) 1,2-Dichloropropane
(22) 1,1,2,2-Tetrachloroethane
(23) Ethylbenzene
(24) 1,3-Dichloropropane
(25) Styrene
(26) Chloromethane
(27) Bromomethane
(28) Bromochloromethane
(29) 1,2,3-Trichloropropane
(30) 1,2,3-Trichlorobenzene
(31) n-Propylbenzene
(32) 1,1,1,2-Tetrachloroethane
(33) Chloroethane
(34) 1,1,2-Trichloroethane
(35) Pentachloroethane
(36) bis-2-Chloroisopropyl ether
(37) sec-Dichloropropane
(38) 1,2,4-Trimethylbenzene
(39) n-Butylbenzene
(40) Naphthalene
(41) hexachlorobutadiene
(42) o-Chlorotoluene
(43) p-Chlorotoluene
(44) 1,3,5-Trimethylbenzene
(45) p-Isopropyltoluene
(46) 1,1-Dichloropropane
(47) iso-Propylbenzene
(48) tert-Butylbenzene
(49) sec-Butylbenzene
(50) Bromobenzene

(f) Analysis for EDB and DBCP shall only be required for community water systems considered vulnerable to contamination by these two VOCs. Vulnerable is defined for this paragraph as those systems potentially contaminated by DBCP and EDB, including surface water systems where these two compounds are applied, manufactured, stored, disposed of or shipped upstream and for ground water systems where the compounds are applied, manufactured, stored, disposed of or shipped in the ground water recharge basin.

(g) Analysis under this subsection shall be conducted using EPA methods 502.1, "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography," 503.1; "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography," or 524.1; "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry". These methods are contained in "Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water," June 1985, available from Environmental Monitoring and Support Laboratory (EMSL), EPA, Cincinnati, Ohio 45268. Vinyl chloride shall be measured using only methods 502.1 or 503.1. Analysis of 1,2-dibromoethane (EDB) and 1,2-dibromo-3-chloropropane (DBCP) shall be conducted by Method 504, "Measurement of 1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-chloropropane (DBCP) in Drinking Water by Microextraction and Gas Chromotagraphy," August 1985, available from EMSL, Cincinnati, Ohio 45268.

(h) Analysis under this section shall only be conducted by laboratories that have been certified for THM analysis and have analyzed Performance Evaluation samples provided by EMSL to within ±40% of the reference value.

(i) States have the authority to use monitoring data collected up to three years prior to this regulation provided that the requirements of this section are met.

7. It is proposed that a new Subpart G (§§ 141.60 through 141.69) be added to read as follows:

* * * * *

Subpart G—National Revised Primary Drinking Water Regulations: Maximum Contaminant Levels

141.60 Effective dates.
141.61 Maximum contaminant levels for organic contaminants.
141.62–141.68 [Reserved]
141.69 Criteria and procedures for public water systems using point-of-use devices and point-of-entry devices; use of bottled water.

Subpart G—National Revised Primary Drinking Water Regulations: Maximum Contaminant Levels

§ 141.60 Effective dates.

(a) For § 141.61(a) (1)–(8), the effective date is [insert date 18 months after publication date of Final Rule].

(b) [Reserved]

§ 141.61 Maximum contaminant levels for organic contaminants.

(a) The following maximum contaminant levels for organic contaminants apply to community water systems.

Contaminant	Maximum contaminant level in mg/l
(1) trichloroethylene	0.005
(2) carbon tetrachloride	.005
(3) vinyl chloride	.001
(4) 1,2-dichloroethane	.005
(5) benzene	.005
(6) 1,1-dichloroethylene	.007
(7) 1,1,1-trichloroethane	.20
(8) p-dichlorobenzene	.75

(b) [Reserved.]

§§ 141.62–141.68 [Reserved]

§ 141.69 Criteria and Procedures for Public Water Systems using Point-of-Use Devices and Point-of-Entry Devices; Use of Bottled Water.

(a) Public water systems may use point-of-use/point-of-entry devices to comply with maximum contaminant levels only if they follow the requirements of this section.

(b) It is the responsibility of the public water system to own, operate, and maintain the point-of-use/point-of-entry treatment system.

(c) The utility must develop a plan and obtain State approval for a monitoring scheme before point-of-use/point-of-entry devices are installed for compliance. This monitoring scheme must provide health protection equivalent to a monitoring scheme for central water treatment.

(d) Effective technology must be properly applied under a plan approved by the State and the microbiological safety of the water must be maintained.

(1) The State must require adequate certification of performance, field testing, and a rigorous engineering design review of the point-of-use/point-of-entry devices proposed.

(2) The design and application of the proposed point-of-use/point-of-entry devices must consider the tendency for increase in heterotrophic bacteria concentrations in water treated with activated carbon. It may be necessary to use frequent backwashing, post-contactor disinfection, and Heterotrophic Plate Count monitoring to ensure that the microbiological safety of the water is not compromised.

(e) All consumers shall be protected. Every building connected to the system must have the point-of-use/point-of-entry device installed, maintained, and adequately monitored. The State must be assured that every building is covered by treatment and monitoring, and that the rights and responsibilities of the utility customer convey with title upon sale of property.

(f) Under the plan approved by the State, point-of-use/point-of-entry devices must provide health protection equivalent to central water treatment.

(g) Bottled water shall not be used to achieve compliance with an MCL except in emergency situations to avoid unreasonable risk.

PART 142—[AMENDED]

8. The authority citation for 40 CFR Part 142 is revised to read as follows:

Authority: 42 U.S.C. 300g-2, 300g-3, 300g-4, 300g-5, 300j-4 and 300j-9.

9. It is proposed that a new § 142.61 be added to Part 142 of Title 40 to read as follows:

§142.61 Variances from the maximum contaminant level for volatile organic chemicals.

(a) The Administrator, pursuant to Section 1415(a)(1)(A) of the Act, hereby identifies the following as the best technology, treatment techniques, or other means generally available for achieving compliance with the maximum contaminant level for volatile organic chemicals (§ 141.12(a) (1)–(9)): Removal using packed tower aeration; removal using granular activated carbon adsorption.

(b) The Administrator, in a State that does not have primary enforcement responsibility or a State with primary enforcement responsibility (primacy State) that issues variances, shall require community water systems to install and/or use any treatment method identified in § 141.61(a) as a condition for granting a variance unless the Administrator or primary State determine that such treatment method identified in § 142.61 is not available and effective for VOC removal for the system. A treatment method shall not be considered to be technically "available and effective" for an individual system if the treatment method would not be technically appropriate and technically feasible for that system or would only result in a marginal removal of VOCs for that system. If, upon application by a system for a variance, the Administrator or primacy State that issues variances determines that none of the treatment methods identified in paragraph (a) of this section is technically available and effective for the system, that system shall be entitled to a variance under the provisions of Section 1415(a)(1)(A) of the Act. The Administrator's or primacy State's determination as to the availability and effectiveness of such treatment methods shall be based upon studies by the system and other relevant information. If a system submits information intending to demonstrate that a treatment method is not available and effective for VOC removal for that system, the Administrator or primacy State shall make a finding whether this information supports a decision that such treatment method is not available and effective for that system before requiring installation and/or use of such treatment method.

(c)(1) Pursuant to § 142.43 (c)–(g) or corresponding State regulations, the Administrator or primacy State that issues variances shall issue a schedule of compliance that requires the system being granted the variance to examine the following treatment methods: (i) To determine the probability that any of these methods will significantly remove VOCs from the water of that system, and (ii) if such probability exists, to determine whether any of these methods are technically feasible and economically reasonable, and that the VOC removals obtained will be commensurate with the costs incurred with the installation and use of such treatment method for that system:

(c)(2) Removal using other waterfall aeration technologies, such as:

(i) Multiple tray aeration, spray aeration, or cascade aeration.

(ii) Removal using diffused or mechanical aeration.

(iii) Removal using powered activated carbon adsorption.

(iv) Use of an alternate source of water.

(d) If the Administrator or primacy State that issues variances determines that a treatment method identified in paragraph (c) of this section is technically feasible, economically reasonable, and will achieve VOC removals commensurate with the costs incurred with the installation and/or use of such treatment method for the system, the Administrator or primacy State shall require the system to install and/or use that treatment method in connection with a compliance schedule issued under the provisions of section 1415(a)(1)(A) of the Act. The Administrator's or primacy State's determination shall be based upon studies by the system and other relevant information.

(e) Use of bottled water under paragraphs (c) and (d) of this section shall not be allowed under a variance except in emergency conditions to avoid unreasonable risk to health.

Appendix A.—Guidance To Determine Vulnerability of Public Water Systems to Contamination by VOCs

Note.—Appendix A will not appear in the Code of Federal Regulations.

EPA's evaluation of available occurrence data has shown that no single factor can perfectly predict the presence or absence of volatile organic chemicals (VOCs) in a water supply. However, size and proximity of a water source to VOC use increases the probability of contamination. If VOCs have been detected in the water source from previous monitoring, the system is considered vulnerable. Other criteria briefly mentioned below may be used by the States and EPA as vulnerability criteria to prioritize systems in implementing the monitoring schedule and to determine the frequency of repeat monitoring. The three general criteria of population, nearby use of VOCs, water source protection, are suggested for developing more specific guidelines to classify community water systems (CWS) as vulnerable.

1. Population

The number of persons served by the CWS has been strongly linked to occurrence in many drinking water sources. Large CWS's, serving populations of 3300 or more are considered vulnerable. To rank the remaining CWS serving populations smaller than 3300, the following information should be considered:

(1) Previous measurements of VOCs in non-potable water samples. Occurrences in non-potable wells or streams may indicate a presence of VOCs in a source that may later contaminate potable water supplies.

(2) Proximity of a smaller system to a larger community may increase the vulnerability of the smaller system because nearby discharges into surface waters, or into ground water recharge areas, can contaminate local drinking water supplies.

(a) Proximity of a surface water system to a larger community can be defined in terms of the flow rates between the monitoring points.

(b) Proximity is harder to define for ground water systems; possibilities include:

(i) Determining hydraulic gradients and travel times between the smaller CWS well(s) and the contamination source. Ground water modeling can be useful, especially when the geology or the well field pumping patterns are complex or uncertain.

(ii) Defining "nearby" statistically, by means of Standard Metropolitan Statistical Areas.

2. Nearby Use of VOCs

A hierarchy of use can be established for a State or regional watershed area or ground water basin.

High volume use: metal fabricators, solvent producers, electroplating plants, airfields, military bases, Superfund sites, closed wells, and a history of large spills are all indicators of the potential for significant presence of VOCs in or near drinking water sources.

Light volume use: electronic component, dry cleaner and small commercial users, protected surface impoundments are examples.

It is likely that more than one of these use categories will apply to the area

served by a single CWS. The combined effect of all on the nearby drinking water sources will have to be evaluated carefully.

3. Protection of the Water Source

The source may be protected by natural factors or discharge controls.

For surface water sources, a sanitary survey and an examination of upstream waste water dischargers (NPDES permittees) can indicate the nature and extent of pollution activities that affect the vulnerability of a surface water system. Some watersheds are protected by strict access and land use laws. Surface water systems could be ranked according to the extent of watershed protection afforded by either these land use restrictions or the remoteness of the source from VOC-based activities.

Ground water sources can be protected naturally by geological formations above the aquifer that are impermeable to VOCs used or stored near the surface, or by strict aquifer management practices. Two problems exist. First, even geologically invulnerable formations can be polluted by improper well construction or discharging into existing wells. Second, because of the complex nature of ground water hydrogeology, it is difficult to regulate and monitor land-use as effectively as for surface water sources.

Rating the vulnerability of ground water systems will often require simultaneously considering aquifer protection and nearby use of VOCs. It is important to characterize the recharge areas by:

- locating all industrial, commercial or municipal facilities that handle wastes or use solvents,
- identifying geological materials that are porous, fractured or have solution openings near VOC sources that overlap the cones of influence of drinking water wells, and
- locating abandoned wells, which can be a sign of faulty well construction, an opportunity for improper dumping, or the existence of a contaminated well.

These three criteria should be used by individual States to devise specific guidelines for the classification of their CWS for the initial round of monitoring. These criteria, along with initial monitoring results, may also be applied to setting a repeat monitoring frequency. Although the regulations specify when systems are to complete the initial monitoring, States are encouraged to accelerate monitoring for the most vulnerable systems.

Appendix B

Options

VOCs: Compliance Monitoring and Monitoring for Unregulated VOCs

Note.—Appendix B will not appear in the Code of Federal Regulations.

Provided below are three options for regulations for compliance monitoring and monitoring for unregulated VOCs. These options are summarized in Table B-1.

In each option, requirements are displayed for (1) an initial round of monitoring and (2) repeat monitoring. In addition, different requirements are set within each option for ground water systems (about 45,000) and surface water systems (about 15,000). The primary differences between the options relate to the extent of specific sampling requirements and the provision of State discretion.

Option 1

This option would require all ground and surface water systems to monitor at least once over four years. Relatively stringent federally mandated sampling requirements would be set. Monitoring for unregulated VOCs would be repeated in 10 years.

Initial Monitoring

- All systems monitor once over 4 years
- Phase in by size:

>10,000; complete by end of 1 year
3300–10000; complete by end of 2 years
<3300; complete by end of 4 years

- Ground water systems:

—Sample locations

- Compliance monitoring: sample at each entry point to the distribution system.
- Unregulated VOCs: sample at each entry point to the distribution system.

—Number of samples

- Compliance monitoring: quarterly sampling for one year (i.e., 4 samples). Require resample of any positive result.
- Unregulated VOCs: one sample and require resample of any positive result.
- Surface Water Systems.

—Sample locations: sample in distribution system at points representative of each source.
—Number of samples: monthly for one year, require resample of any positive result.

- Costs for initial monitoring.

—Compliance: $25 million per year for four years (total $100 million)
—Unregulated: $2.7 million per year for four years (total $10.8 million)

Repeat Monitoring

All systems would be required to remonitor for the nine VOCs on a frequency based upon the results of the first monitoring and their vulnerability to VOC contamination. All systems would be required to repeat the monitoring for unregulated VOCs in 10 years (for unregulated VOCs that were detected in the initial monitoring it would be anticipated that States would require follow-up investigative monitoring).

Status [1]	Frequency
Compliance Monitoring:	
VOCs not detected and invulnerable.	Repeat in 5 years
VOCs not detected and vulnerable.	Repeat in 3 years.
VOCs detected	Monthly.
Monitoring for unregulated	Repeat in 10 years.

[1] States would recertify annually vulnerability status.
[2] Any system installing aeration or GAC would be required to monitor monthly to assure treatment effectiveness. After a baseline of data was generated States could decrease the frequency to quarterly.

- Costs for repeat monitoring.

—Compliance monitoring: $64 million/year
—Unregulated monitoring: $2.7 million/year

Option 2

This option would require all ground and surface water systems to monitor at least once over four years. Fewer samples would be required during the first round of monitoring than in Option 1. Ground water systems would be required to repeat compliance monitoring at a frequency based upon vulnerability and monitoring results. Repeat monitoring by surface water systems would be at State discretion. No repeat monitoring for unregulated VOCs would be federally mandated.

Initial Monitoring

- All systems monitor once over 4 years.
- Phase in by size:

>10,000; complete by end of 1 year.
3300–10000; complete by end of 2 years.
<3300; complete by end of 4 years.

- Ground water systems:

—Sample locations

- Compliance monitoring: sample at each entry point to the distribution system.
- Unregulated VOCs: sample at each entry point to the distribution system.

—Number of samples

- Compliance Monitoring: quarterly sampling for one year; if first sample detects no VOCs, State can reduce

monitoring to that one sample. State discretion on confirmation sample.

• Unregulated VOCs: one sample; State discretion on confirmation sample.

• Surface Water Systems.

—Sample locations: Sample in distribution system at points representative of each source.

—Number of samples: Quarterly for one year; State discretion on confirmation samples.

• Cost for initial monitoring.

—Compliance: $9.3 million per year over four years (total $37 million)

—Unregulated: $2.3 million per year over four years (total $8 million)

Repeat Monitoring

Repeat compliance monitoring would be based upon vulnerability and if VOCs were detected, similar to Option 1. Repeat compliance monitoring for surface water systems would be at State discretion. Repeat monitoring for unregulated VOCs would be at State discretion.

Status [1]	Frequency
Compliance Monitoring:	
VOCs not detected and invulnerable.	Repeat in 5 years.
VOCs not detected and vulnerable.	Repeat in 3 years.
VOCs detected	Quarterly.
Monitoring for unregulated	State discretion.

[1] States would recertify annually vulnerability status.

• Cost for repeat monitoring.

—Compliance: $17 million per year

—Unregulated: $0

Option 3

This option would require all ground water systems to monitor at least once over five years. Monitoring of surface waters would be at State discretion based upon vulnerability. Monitoring for unregulated VOCs would only require samples representing 25% of the wells in each ground water system. State discretion would be provided for repeat sampling frequencies for systems not detecting VOCs in the first round. No repeat monitoring would be required for unregulated VOCs.

Initial Monitoring

• All systems monitor once over five years

• Phase in by size:

≤10,000; Complete by end of 1 year.

3300–10000; Complete by end of 2 years.

500–3300; Complete by end of 4 years.

<500; Complete by end of 5 years.

• Ground Water Systems.

—Sample locations.

• Compliance monitoring: sample entry points to the distribution system.

• Unregulated VOCs: sample at entry points to the distribution system.

—Number of Samples

• Compliance monitoring: one sample; State discretion on confirmation sample.

• Unregulated VOCs: number representing 25% of wells in each system. State discretion on confirmation sample.

• Surface Water System: State discretion based upon vulnerability assessment.

• Costs for initial monitoring.

—Compliance: $3.8 million over 5 years (total $20 million)

—Unregulated: $0.5 million over 5 years (total $1.5 million)

Repeat Monitoring

Repeat compliance monitoring would only be for those systems that detected VOCs in the first round. Other systems would be at State discretion. No federally required repeat monitoring for unregulated VOCs.

Status [1]	Frequency
VOCs not detected and invulnerable.	State discretion.
VOCs not detected and vulnerable.	State discretion.
VOCs detected	Annually.

[1] States recertify annually vulnerability status.

• Costs of repeat monitoring

—Compliance: $2.9 million/year

—Unregulated: $0

Other Factors for Reduction in Monitoring

• Require sampling for vinyl chloride only in ground water systems that had detected other chlorinated 2-carbon VOCs.

• Systems with recent valid monitoring data would not be required to conduct the monitoring; i.e., "grandfather" waiver. Minimum QA requirements would have to be met.

• States could reduce monitoring for ground and surface water systems that detected VOCs below the MCL after a baseline period of data are generated.

• States would reduce monitoring for systems that took a well out of service that had detectable levels of VOCs.

TABLE B-1.—SUMMARY: MONITORING OPTIONS

	Option 1	Option 2	Option 3
Initial Round:			
Time to Complete	4 years	4 years	5 years.
Ground Water Systems:			
Compliance [1]	Quarterly: 4 samples/confirmation	Quarterly: State can reduce to 1 sample	1 sample.
Unregulated	1 sample/confirmation	1 sample/State discretion on confirmation.	1 sample at 25% of wells.
Surface Water Systems:			
Compliance and Unregulated	Monthly for one year	Quarterly for one year	State Discretion.
Costs:			
Compliance	$25 million/year	$9.3 million/year	$3.8 million/year.
Unregulated	$2.7 million/year	$2.3 million/year	$0.5 million/year.
Repeat Monitoring:			
Compliance [1]			
VOCs ND/Invulnerable	5 years	5 years	State Discretion.
VOCs ND/Vulnerable	3 years	3 years	State Discretion.
VOCs detected	Monthly	Quarterly	Annually (State Systems). State Discretion. (Surface Water Systems).
Unregulated	10 years	State discretion	None.
Costs:			
Compliance	$64 million/year	$17 million/year	$2.9
Unregulated	$2.7 million/year	$0	$0

[1] Vinyl chloride would only be required for systems that had detected other chlorinated 2-carbon VOCs. No requirements for vinyl chloride in surface water systems.

[FR Doc. 85-26416 Filed 11-12-85; 8:45 am]

BILLING CODE 6560-50-M

Federal Register

Wednesday
November 13, 1985

Part IV

Environmental Protection Agency

40 CFR Part 141

National Primary Drinking Water Regulations; Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[OW-FRL-2858-7]

National Primary Drinking Water Regulations; Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rulemaking.

SUMMARY: This proposed rule under the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*) would establish Recommended Maximum Contaminant Levels (RMCLs) for synthetic organic chemicals (SOCs), inorganic chemicals (IOCs) and microbiological parameters in drinking water. Proposed RMCLs (goals) for substances considered to be probable human carcinogens are set at the zero level and RMCLs for substances not treated as probable human carcinogens are set based upon chronic toxicity or other data. SOCs, IOCs and microorganisms that are not included in this proposal may be considered for subsequent rulemaking under the Safe Drinking Water Act.

RMCLs are *non-enforceable health goals* which are to be set at levels which would result in no known or anticipated adverse health effects with an adequate margin of safety. This proposal is the initial stage in rulemaking for the establishment of primary drinking water regulations for the SOCs, IOCs and microbials. Following this proposal, Maximum Contaminant Levels (MCLs) and monitoring/reporting requirements will be proposed when the RMCLs are promulgated. MCLs are *enforceable standards* and are to be set as close to the RMCLs as is feasible and are based upon treatment technologies and cost.

Public comments are solicited on each of the proposed RMCLs as well as on the regulatory approach being considered. Specific scientific and technical reviews and comments are requested on the support documents on analytical methods and health effects.

The notice and supporting documentation also contains calculations and information regarding risks from contaminants that EPA is proposing not to regulate. EPA has published nonregulatory Drinking Water Health Advisories on these contaminants. Public comment is also requested on the scientific basis for those calculations and whether EPA should develop Primary Drinking Water Regulations, or Health Advisories, or take no action.

DATES: Written comments should be submitted by March 13, 1986. A public hearing will be held in Washington, D.C. on January 28 and 29, 1986, beginning at 9:00 am in Conference Room 1, adjacent to the Washington Information Center, EPA, 401 M Street SW., Washington, DC.

ADDRESSES: Send written comments to Comment Clerk, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. A copy of the comments and supporting documents will be available for review during normal business hours at the EPA, Room 2904 (rear), 401 M Street SW., Washington, DC 20460. It is requested that anyone planning to attend the public hearing (especially those who plan to make statements) register in advance by calling or writing Ms. Arnetta Davis at 202/382-7575, EPA, WH-550, 401 M Street SW., Washington, DC 20460. Persons planning to make statements at the hearing are encouraged to submit written copies of their remarks at the time of the hearing.

Supporting documents cited in Section XI will be available for inspection at the Drinking Water Supply Branches in EPA's Regional Offices.

I. JFK Federal Bldg., Boston, MA 02203, Phone: (617) 223-6486, Jerome Healy
II. 26 Federal Plaza, Room 824, New York, NY 10278, Phone: (212) 264-1800, Walter Andrews
III. 6th & Walnut Sts., Philadelphia, PA 19106, Phone: (215) 597-9873, Bernie Sarnowski
IV. 345 Courtland Street, Atlanta, GA 30365, Phone: (404) 881-3781, Robert Jourdan
V. 230 S. Dearborn St., Chicago, IL 60604, Phone: (312) 886-6176, Joseph Harrison
VI. 1201 Elm St., Dallas, TX 75270, Phone: (214) 767-2620, James Graham
VII. 726 Minnesota Ave., Kansas City, KS 66101, Phone: (913) 236-2815, Gerald R. Foree
VIII. 1860 Lincoln St., Denver, CO 80295, Phone: (303) 293-2815, Marc Alston
IX. 215 Fremont St., San Francisco, CA 94105, Phone: (415) 974-8076, Leslie Ragle
X. 1200 Sixth Ave., Seattle, WA 98101, Phone: (206) 442-1225, Jerry Opatz.

Copies of draft health criteria, occurrence, analytical methods and health advisory documents will be available for a fee from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285, Port Royal Road, Springfield, Virginia 22161. The toll free number is 800/336-4700; local: 703/487-4650.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, telephone (202) 382-7575.

Table of Contents

I. Statutory Requirements
II. Regulatory Framework
III. Regulatory Background
  A. Interim Regulations
  B. National Academy of Sciences (NAS)
  C. Issues Being Addressed in Revised Regulations
  D. Summary of Comments
IV. Regulatory Alternatives
V. Factors in the Development of RMCLs
  A. Selection of Contaminants for Regulation
  B. Sources of Occurrence and Human Exposure Data
  C. Evaluation of Health Effects and Determination of RMCLs
    1. Non-carcinogens—AADIs
    2. Calculation of the RMCLs
    3. Short-term Assessments
    4. Carcinogens
    5. Evidence of Carcinogenicity
VI. Microbiological RMCLs
  A. Interim Regulations and Recent Outbreaks of Waterborne Disease
  B. Total Coliform Bacteria
  C. Turbidity
  D. Giardia
  E. Pathogenic Viruses
  F. Legionellae
  G. Heterotrophic Bacteria
  H. Treatment Technique Requirements
    1. Mandatory Filtration and Disinfection of Surface Water for Microorganisms
    2. Mandatory Disinfection of Ground Water
VII. Inorganic RMCLs
  A. Availability of Analytical Methods
  B. Proposed RMCLs
    1. Arsenic
    2. Asbestos
    3. Barium
    4. Cadmium
    5. Chromium
    6. Copper
    7. Lead
    8. Mercury
    9. Nitrate and Nitrite
    10. Selenium
  C. IOCs for Which RMCLs are not Proposed
    1. Aluminum
    2. Cyanide
    3. Molybdenum
    4. Nickel
    5. Silver
    6. Sulfate
    7. Sodium
    8. Antimony, Beryllium, Thallium and Vanadium
    9. Zinc
VIII. Synthetic Organic Chemicals: RMCLs
  A. Availability of Analytical Methods
  B. Proposed RMCLs
    1. Acrylamide
    2. Alachlor

3. Aldicarb, Aldicarb sulfoxide and Aldicarb sulfone
4. Carbofuran
5. Chlordane
6. Dibromochloropropane
7. o-, m-Dichlorobenzene
8. cis- and trans-1,2-Dichloroethylenes
9. 1,2-Dichloropropane
10. 2,4-D
11. Epichlorohydrin
12. Ethylbenzene
13. Ethylene dibromide
14. Heptachlor and Heptachlor epoxide
15. Lindane
16. Methoxychlor
17. Monochlorobenzene
18. Polychlorinated biphenyls
19. Pentachlorophenol
20. Styrene
21. Toluene
22. Toxaphene
23. 2,4,5-TP
24. Xylene
C. RMCLs Not Proposed
1. Atrazine
2. 2,3,7,8-Tetrachlorodibenzo-p-dioxin
3. Endrin
4. Hexachlorobenzene
5. Simazine
6. Other SOCs
IX. Impact of this Regulation
X. Public Docket
XI. Request for Public Comment

List of Figures and Tables

Figure 1—National Primary Drinking Water Regulations Regulatory Procedure
Table 1—Recommended Actions on ANPRM Contaminants
Table 2—Guidelines on the Use of Uncertainty Factors
Table 3—Three-Category Approach for Setting RMCLs
Table 4—Preliminary Classification of SOCs and IOCs into Three Category Approach
Table 4A—Classification of SOCs and IOCs based upon Proposed EPA Guidelines
Table 5—RMCL Options for Category II contaminants
Table 6—Proposed RMCLs for Microorganisms
Table 7—Interim Regulations: Microorganisms
Table 8—Proposed RMCLs for IOCs
Table 9—Short-term Assessments for IOCs for Which RMCLs are Proposed
Table 10—Short-term Assessments and Provisional AADIs for IOCs for Which RMCLs are not Proposed
Table 11—Analytical Methods for IOCs
Table 12—Proposed RMCLs and AADIs for SOCs Proposed for Regulation
Table 13—Risk Estimates for SOCs for Which Data were Available
Table 14—Short-term Assessments and Provisional AADIs for SOCs for Which RMCLs are not Proposed
Table 15—Short-term Assessments for SOCs for Which RMCLs are Proposed
Table 16—Analytical Methods for SOCs

I. Statutory Requirements

The Safe Drinking Water Act (42 U.S.C. 300f, *et seq.*) ("SDWA" or "the Act") requires the EPA to establish primary drinking water regulations which: (1) Apply to public water systems; (2) specify contaminants which in the judgment of the Administrator, may have any adverse effect on the health of persons; and (3) specify for each contaminant either (a) maximum contaminant levels (MCLs) or (b) treatment techniques. See Section 1401(1), 42 U.S.C 300f. A treatment technique requirement would be set only if "it is not economically or technologically feasible" to ascertain the level of a contaminant in drinking water.

The SDWA includes provisions for interim and revised regulations. See section 1412, 42 U.S.C. 300g–1. Interim regulations were to be established within 180 days of enactment of the SDWA. Revised regulations are to be developed in two steps: the Agency is to establish recommended maximum contaminant levels (RMCLs) and then establish maximum contaminant levels (MCLs) as close to the RMCLs as feasible. MCLs are to be proposed at the time of promulgation of the RMCLs.

RMCLs are non-enforceable health goals. RMCLs are to be set at a level which, in the Administrator's judgment, "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". Section 1412(b)(1)(B). The House Report on the 1974 legislation provides congressional guidance on developing RMCLs:

> . . . the recommended maximum level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at zero level.

House Report No. 93–1185, July 10, 1974, at 20. In addition, a list of contaminants is to be included in the regulations for "any contaminant the level of which cannot be accurately enough measured in drinking water to establish a Recommended Maximum Contaminant Level and which may have any adverse effect upon the health of persons." 1412(b)(1)(B).

MCLs are the enforceable standards. MCLs must be set as close to RMCLs as is feasible. Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)." Section 1412(b)(3).

Even though RMCLs are promulgated, no system is forced to reduce contaminants to this level or to take other action regarding contaminants. RMCLs only serve as goals for the Agency in the course of setting MCLs and are therefore initial steps in the MCL rulemaking that will follow. In some cases, the MCLs will be set very close to the RMCLs; in other cases, analytical methods, control processes or cost considerations may dictate an MCL that is not as close. Public water systems must comply with the MCL; non-compliance with an RMCL cannot be the basis of an enforcement action under section 1414 of the Safe Drinking Water Act.

II. Regulatory Framework

Issuing Revised Primary Drinking Water Regulations is the second step in the evolution of the primary drinking water regulations mandated by the SDWA.

In the *first step*, the National Interim Primary Drinking Water Regulations were promulgated on December 24, 1975, with an effective date of June 24, 1977. Amendments were issued in 1976, 1979 and 1980. See 40 CFR Part 141. Maximum contaminant levels (MCLs) and monitoring and reporting requirements were set for numerous microbiological, inorganic, organic, and radionuclide contaminants (40 CFR Part 141, Subpart B).

Section 1412(e) of the SDWA directed EPA to arrange for the National Academy of Sciences (NAS) or an equivalent organization to conduct a study to assess the health effects of contaminants in drinking water and to provide proposals for RMCLs.

As the *second step*, section 1412(b)(1)(B) provided that EPA must propose and promulgate National Revised Primary Drinking Water

Regulations (NPDWR) that would include RMCLs, MCLs and monitoring and reporting requirements for those contaminants that may have any adverse effect on human health.

Development of the NPDWR will be accomplished in four phases:

- Phase I Volatile Synthetic Organic Chemicals.
- Phase II Synthetic Organic Chemicals, Inorganic Chemicals and Microbiological Contaminants.
- Phase IIA Fluoride.
- Phase III Radionuclides.
- Phase IV Disinfectant By-Products including Trihalomethanes.

This notice is Phase II—proposal of RMCLs for certain inorganic, organic and biological contaminants. Because of the great number of possible substances to be considered, additional drinking water contaminants from these three groups will be considered in later iterations of NPDWR.

In general, the procedure for all four phases will be similar as is shown in Figure 1. Generally, it requires approximately one year for each major regulatory action (e.g., RMCL to proposal). The status of each Phase is provided below:

- Phase I:

ANPRM, March 4, 1982 47 FR 9350
Public Meeting, April 26, 1982
Four Public Workshops, June–August 1982
RMCL Proposal, June 12, 1984 49 FR 24330
Final RMCL rule/MCL Proposal, Scheduled for October 1985

- Phase II:

Microbiological Workshop, December 4, 1981
ANPRM, October 5, 1983 48 FR 45502
Four Public Workshops, September-December 1983
Public Meeting, December 13, 1983
Final RMCL rule/MCL Proposal, Scheduled for October 1986.

- Phase IIA:

Notice, December 1, 1981 46 FR 58345
ANPRM, October 5, 1983 48 FR 45502
RMCL Proposal, May 14, 1985 50 FR 20164
Final RMCL/MCL Proposal, Scheduled for November, 1985

- Phase III:

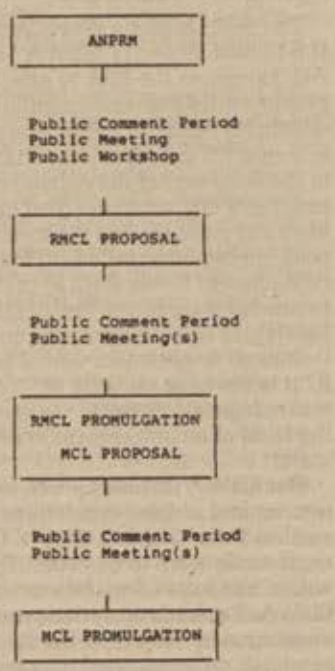
Radionuclides Workshop, May 1983
ANPRM, October 5, 1983 48 FR 45502
RMCL Proposal, Scheduled for December, 1985

- Phase IV, ANPRM Scheduled for 1986

Figure 1

NATIONAL PRIMARY DRINKING WATER REGULATIONS

REGULATORY PROCEDURE



III. Regulatory Background

The discussion in this section provides a brief overview of: (1) The Interim Regulations and the implementation experiences, (2) the National Academy of Sciences (NAS) role in development of the Revised Regulations, (3) areas that will be addressed in the Revised Regulations, and (4) summary of comments on the Phase II ANPRM for these contaminants.

A. Interim Regulations

As required by the SDWA, EPA acted quickly following the passage of the SDWA in publishing Interim Primary Drinking Water Regulations. Regulations were established initially for ten inorganic chemicals, six pesticides and two microbiological indicator contaminants. Amendments were later added on radionuclides, trihalomethanes and corrosion/sodium monitoring. The regulations set MCLs, monitoring and reporting requirements. Analytical methods were specified as well as public notification requirements (40 FR 59566, Radionuclides, 44 FR 68641, 45 FR 57332).

These regulations apply to some 60,000 community water systems and 160,000 non-community water systems. The distinction between community and non-community systems is that non-community systems serve a transient population (as opposed to residential). Only those MCLs in the Interim Regulations thought to have potentially acute health concerns were applied to the non-community systems; these included total coliforms, turbidity and nitrate.

RMCLs were not established in the Interim Regulations because the SDWA only specifies that RMCLs are to be set in establishing the Revised Regulations. The MCLs in the Interim Regulations were to:

"protect health to the extent feasible, using technology, treatment techniques, and other means which the Administrator determines are generally available (taking costs into consideration) on the date of enactment of this title." Section 1412(a)(2)

This mandate for Interim MCLs is similar to the MCLs in the Revised Regulations; however, the Revised Regulations are different in two fundamental respects. First, in the Revised Regulations, a goal (i.e., the RMCL) is established and then the MCL is set as close to the goal as is feasible. RMCLs are to be established for a comprehensive number of contaminants. This proposal deals with the RMCLs. Second, in setting MCLs, feasible is defined in the SDWA as using the *best* (emphasis added) technology, treatment techniques, and other means which the Administrator finds are generally available (taking costs into consideration).

B. National Academy of Sciences (NAS)

Under the SDWA, NAS is charged with assessing the following:

- Summary/evaluation of relevant publications and studies.
- Methodologies/assumptions used in estimating levels at which adverse effects occur.
- Methodologies/assumptions for estimating margin of safety for drinking water regulations.
- Develop proposals for RMCLs.
- List of contaminants the level of which cannot be determined in drinking water that pose a health risk.
- Research priorities.

While the NAS did not provide proposals of RMCLs, the NAS has provided guidance on the above items and on the toxicological effects of numerous drinking water contaminants. The five volumes of *Drinking Water and Health* include the following:

Volume I (1977)

- Safety and risk assessment procedures.

• Toxicity of organic, inorganic, microbial and radionuclide contaminants.

Volume II (1980)

• Disinfection of drinking water.
• Chemistry of disinfection in drinking water.
• Granular activated carbon.

Volume III (1980)

• Epidemiology studies.
• Problems of risk estimation.
• Toxicity of selected contaminants.
• Nutritional aspects of drinking water contaminants.

Volume IV (1982)

• Distribution system potential health problems.
• Toxicity of inorganic and organic chemicals.

Volume V (1983)

• Toxicity of selected contaminants.
• Epidemiology of arsenic and asbestos.

Because the NAS did not provide proposed RMCLs, the Agency has developed the proposed RMCLs in this notice based upon its own evaluations which included the NAS reports along with other pertinent data.

C. Issues Being Addressed in Revised Regulations

As directed by the SDWA, the Revised Regulations will address a wide variety of problems in drinking water quality in public water systems across the United States. Much experience has been gained from the implementation of the Interim Regulations and a comprehensive review and revision of the provisions of the Interim Regulations is being undertaken during development of the Revised Regulations. In addition, new problems in drinking water quality have been discovered that will be addressed in the Revised Regulations. Under the requirements and definitions of the SDWA, the basic questions being considered in the efforts include:

• For which contaminants should regulations be set?
• What levels for the RMCLs and MCLs would be appropriate?
• What monitoring and reporting requirements would be appropriate?

The Advance Notice of Proposed Rulemaking (ANPRM), issued October 5, 1984 (48 FR 45502), provided the public with an opportunity to review the issues and comment to the Agency early in the development stages. The ANPRM was followed by four public technical workshops and a public meeting during which the regulatory and scientific issues were discussed. The public comments received on the ANPRM are discussed in this section, Part D.

This proposal addresses only the selection of contaminants for possible regulation and the proposed RMCLs for these substances. Public comments and workshop results addressing MCLs and monitoring and reporting requirements will be addressed in the MCL proposal which will be published with the promulgated RMCLs. However, to provide some perspective on approaches being considered for the regulations, a brief overview of problems that will be considered in the development of the RMCLs, MCLs, and monitoring and reporting requirements is provided below.

Implementation of the Interim Regulations has shown the following major areas of concern:

• Compliance by Small Systems

For the most part, compliance problems with the MCLs and monitoring and reporting requirements have generally been associated with small systems. Resources are often limited in small systems and when a drinking water problem is present, the small systems generally are least able to cope with it.

Variances may be granted when a system, "because of characteristics of the raw water sources which are reasonably available to the systems, cannot meet the requirements . . . despite application of the best technology, treatment techniques, or other means, which the Administrator finds are generally available (taking costs into consideration)." (Section 1415(a)(1)(A)). Variances do not have a fixed date in the law for the system to come into compliance but the system must be put on a compliance schedule requiring compliance as expeditiously as practicable.

The approach to variances in the Revised Regulations would be similar to that promulgated for the trihalomethane regulations (48 FR 8406, Feb. 28, 1983). The best generally available technology (GAT) under section 1415 would be defined for each regulated contaminant, taking cost into consideration and possibly categorizing by system characteristics such as size or water source. States would evaluate each case on a site-specific basis to determine if the identified GAT was appropriate and effective for that system. In addition to central treatment alternatives, decentralized options such as use of bottled water and point-of-use treatment devices are being considered as control measures to reduce contamination until the system can reach compliance with the NPDWR through other means.

• Strength of Evidence of Potential Health Effects

Because of the added costs of treatment, many systems remain out of compliance with several MCLs; some systems remain unconvinced that the net benefits of contaminant reduction is worth the costs. This issue often relates to the availability and strength of evidence of data on potential health effects.

Comprehensive assessments have been conducted of the available information on potential health effects of every contaminant in this proposal. State-of-the-art scientific methods have been utilized in determining the potential health effects. All of the accumulated/analyzed data are summarized and presented for public comment in the Health Effects Criteria Documents referenced in Section X of this notice.

• Monitoring Inflexibility

The Interim Regulations require monitoring to assess compliance with the MCLs at set frequencies for certain contaminants; for example, monitoring for inorganic compounds must be conducted at least once per year or once per three years for supplies using surface or ground water sources, respectively. While monitoring once a year or every three years does not seem to be overly demanding, this can be costly for small systems, and upon those States that conduct monitoring for certain of the systems (e.g., small systems) within their boundaries. States have reported that certain of these inorganic compounds have not been detected at significant levels in the drinking water in many systems and the probability of future contamination is very slight. Monitoring has shown that little change in concentrations occurs over time for certain contaminants, primarily inorganics in ground water. In addition, some contaminants such as the six pesticides in the Interim Regulations have been found only rarely since compliance monitoring requirements went into effect.

To provide for more efficient use of State and local resources, flexibility in monitoring requirements will be a general principle in development of the Revised Regulations. In addition, to assure detection and control of intermittent contaminants or those that are not distributed homogenously, more specific monitoring requirements will be designed. States also will be provided authority to determine specific monitoring frequencies for systems beyond the federal minima. A three-

tiered approach is being considered for determining whether and in what manner to regulate specific contaminants. Contaminants would be divided into three categories:

Tier I—Those which occur with sufficient frequency and which are of sufficient concern to warrant national regulation (MCLs) and consistent monitoring and reporting.

Tier II—Those which are of sufficient concern to warrant national regulation (MCLs) but which occur at limited or predictable frequency, justifying flexible national minimum monitoring requirements.

Tier III—Those which would not warrant development of a regulation but for which non-regulatory health guidance could be provided to States or water systems.

Additional descriptions of the categories can be found in the ANPRM (Oct. 5, 1983, 49 FR 45502).

• Public Notice

The SDWA is very specific in the area of public notice (Section 1414), and public notification requirements in the Interim Regulations are relatively inflexible. The specific media are stated in the law and regulations; however these do not appear always to be the most effective means of notice. The SDWA currently is under review for possible amendment in the area of public notification to allow some flexibility.

• Non-Community Water Systems

Non-community water systems (NCWS) serve transient populations as opposed to residential. Only three MCLs in the Interim Regulations apply to NCWS and these protect against acute health effects. Concerns have been raised about reported human exposure to contaminants in certain types of NCWS, such as schools or factories which consistently serve the same consumers. In addition, monitoring frequencies were similar for all sizes of NCWS regardless of the number of consumers served per day.

The Revised Regulations will address these two situations by considering redefinition of NCWS and possible application of other MCLs with potential chronic health concerns. In addition, monitoring requirements will be evaluated according to the size of the NCWS and other relevant factors.

• Monitoring and Determining Compliance to Accurately Detect Contaminants

In certain systems, problems with exceeding MCLs are experienced continually by a portion of the system; e.g., corrosion by-products or portions of a system using a specific well, well field, or surface water source. If results are averaged, the overall system may be technically in compliance and thus no action (including no public notification) would be required. However, those consumers in the particular problem portion of the distribution system are exposed continually to levels above the MCLs. Similarly, corrosion by-products (e.g., lead) are dependent upon the corrosive characteristics of the drinking water and the distribution system materials; monitoring may not detect any violations of MCLs if not sampled at the proper locations. Sampling techniques also can impact on the level of contamination detected.

These are areas of significant concern and the Revised Regulations will determine the most effective means of calculating compliance. Monitoring requirements will be redesigned to assess more effectively the occurrence of corrosion by-products and human exposure in various parts of distribution systems.

Other areas of concern that will be addressed in the Revised Regulations include:

• Numerous synthetic organic chemicals (SOCs) which have been found at increasing frequencies in drinking water across the country. Essentially, two separate groups of SOCs are being detected.

—Pesticides. Different pesticides have been detected in drinking water in various parts of the country. The extent of the problem is highly dependent upon the pesticide application mode and hydrogeological factors. Pesticide contamination of surface waters appears to be closely related to such factors as rates and times of application and rainfall and run-off. Thus, monitoring results can be misleading if sampling is not done at appropriate times and places.

—Organic Chemicals (industrial uses). Concern is focused primarily upon contamination of ground waters from improper disposal of hazardous wastes; numerous SOCs have been detected in ground water as well as in surface waters although introduction of controls to industrial and municipal effluents apparently has improved surface water quality in recent years.

• Inorganic chemicals have been found to be problems primarily in ground waters and are usually a result of natural contamination by geological formations. In addition, contamination for hazardous waste site run-off and leachates remains a concern. All inorganics in the Interim Regulations will be re-evaluated along with a number of other inorganics that have been detected in drinking water. Some of these include arsenic, barium, nitrate, nitrite, copper, sulfate, asbestos, and sodium.

• The microbiological quality of drinking water continues to be a principal concern in development and eventual implementation of the Revised Regulations. Despite compliance with the Interim Regulations by most water systems, waterborne outbreaks of disease are reported with increasing frequency. Much of this may be attributable to better reporting procedures. Major causes of outbreaks are deficiencies in (or lack of) treatment as well as distribution system problems. The specific etiology of the outbreaks is for the most part unknown; *Giardia lambia* has been identified as a primary agent in many recent outbreaks in all parts of the country. Viruses also have been implicated in a large number of outbreaks. Controls on coliforms and turbidity alone, although highly effective, are not always sufficient to assure the biological safety of drinking water.

D. Public Comments

The ANPRM (October 5, 1983, 48 FR 45502) solicited comments on the technical and regulatory issues that are being examined concerning the development of National Revised Primary Drinking Water Regulations for organic, inorganic, and microbial contaminants in drinking water. See Appendix A for a summary of the public comments received.

IV. Regulatory Alternatives

Either of two philosophies could be followed in determining which substances are appropriate for regulations under the SDWA. The broader view would establish RMCLs and MCLs for as many substances as possible that may be of health concern in drinking water. RMCLs and MCLs would be set for substances on the basis of (1) sufficient health effects information and (2) the occurrence in drinking water or the potential for more widespread occurrence in drinking water.

A more limited view would be to establish RMCLs and MCLs only for those substances which actually occur in public drinking water supplies at or near levels that could result in sufficient public health risk of national scope from drinking water. The limited view would not examine the potential for widespread occurrence in drinking water and thus would not incorporate

an approach for long term anticipatory protection of water supplies; it would essentially wait for widespread contamination to occur before regulatory action would be taken.

The strength of the broad view is that it would provide a single, extensive listing of concentration limits that had been thoroughly and publicly reviewed and that would help to define "potable" drinking water regardless of source. The presence of such a listing may assist response to many situations involving contamination from many infrequently detected substances. Since decisions to act or not to act must be made for every contamination incident, this anticipatory and consistent approach might be the most cost/effective, avoiding case-by-case decisions on the safety of the drinking water. One additional consideration is the intensity of public interest and awareness that some chemical might be in drinking water; the public wants to know if the drinking water is safe; a federal standard provides guidance on this question.

Another situation where regulation may be appropriate under the broad view is for a chemical that has only been detected (in surveys conducted to date) at levels below those associated with potential health risks. The MCL would provide guidance that no action was necessary for these systems with less than that level; without regulations, these types of situations have met widely varying responses by States and public water systems. Regulations can provide a basis for rational and uniform responses to incidents of contamination.

The second, more limited approach to standard setting has the strength of allowing EPA to concentrate its resources on those substances which pose the greatest public health risks from drinking water, reflecting both extent of contamination and the size of populations at risk. Thus, the formal regulatory process would be reserved for the most significant current problems. States or other entities would be forced to address contaminants of more limited scope. This approach would likely lead to a multiplicity of State regulations and the need for a large number of non-regulatory EPA Drinking Water health advisories to fill the gap. Health advisories can be prepared more quickly by EPA because they are limited only to considerations of toxicology (they do not consider technology feasibility and costs) and they would not require rulemaking. On the other hand, health advisories have been adopted by some States as *de facto* standards.

The National Drinking Water Advisory Council (NDWAC) was requested to provide advice on the general philosophical approach to determining which contaminants should be selected for regulation; the Council recommended the following:

> The Council recommends that contaminants be considered for regulation on the basis of sufficient health effects information and the occurrence of contaminants in drinking water and the potential for more widespread occurrence in drinking water.
>
> The minority felt that contaminants should be considered for regulation on the basis of sufficient health effects information and the potential for occurrence in drinking water. It was contended that the aim of the Safe Drinking Water Act is to prevent the occurrence of contaminants in drinking water and waiting to regulate until the contaminant has been detected is not an approach considered to be protective of public health.

The approach followed in this proposal in the broad view that would set RMCLs and MCLs for contaminants of health concern that have been detected in drinking water or have the potential for more widespread occurrence. Public comments are requested on the appropriateness of this approach.

V. Factors in the Development of RMCLs

The SDWA authorizes EPA to establish RMCLs for "each contaminant which, in [the Administrator's] judgment . . . may have any adverse effect on the health of persons". Section 1412(b)(1)(B). A primary drinking water regulation is to be established for each contaminant for which an RMCL is established. Section 1412(b)(2). Presented below are discussions of (1) the factors used to select contaminants for regulation and (2) the methodology and basis for determining what levels are appropriate for the RMCLs.

A. Selection of Contaminants for Regulation

This section provides a discussion of the factors used to select the specific contaminants for which RMCLs are proposed at this time. SOCs, IOCs and microbials that were not included in this proposal will be reconsidered in later iterations of the Revised Reguations as additional data become available. The reader also is referred to the RMCL proposal for VOCs (49 FR 24330) for additional discussion on which factors are considered in selecting contaminants for regulation.

Other than the above directive of the SDWA, little additional guidance was provided upon which to determine how to select contaminants for regulation under the SDWA. Obviously, it is impossible to consider for regulation every chemical that may appear in drinking water and that theoretically may adversely affect health in some remote circumstances. What is needed is some priority of contaminants for regulation adversely affect health in some remote circumstances. What is needed is some priority of contaminants for regulation so that a reasonable number of contaminants of sufficient concern can be addressed in regulations that will advance the goals of the SDWA and provide definitive guidance to address potential human health effects of exposure to hazardous materials in drinking water. To accomplish this, EPA could adopt criteria from which to select contaminants for possible regulation under the SDWA. The most relevant criteria for selection of contaminants are: (1) The analytical ability to detect a contaminant in drinking water, (2) the potential health risk, and (3) the occurrence or potential for occurrence in drinking water.

A set of selection criteria have been developed which essentially expand the three primary factors listed above. Use of a specific formula to apply selection criteria is not believed to be appropriate because of the many variables associated with contaminants in drinking water; however, a decision-making "logic train" has been developed which incorporates the selection criteria and provides a framework from which to make appropriate determinations. Given the variability associated with exposure and human health aspects of drinking water contaminants and the directives of the SDWA, the decision criteria must remain flexible such that a case-by-case decision can be made for each contaminant. However, the decision criteria do set forth an operative framework. For each contaminant, the essential factors in the analysis are as follows:

- Is an analytical method available to detect the contaminant in drinking water? If EPA cannot ascertain whether the contaminant can be found in drinking water, a regulation may not be appropriate.
- Are there sufficient health effects data upon which to make a judgment on an RMCL or health advisory?
- Are there potential adverse health effects from exposure to the contaminant via ingestion?
- Does the contaminant occur in drinking water?

—Has the contaminant been detected in significant frequencies and in a widespread manner?

—If data are limited on the frequency and nature of contamination, is there

a significant potential of drinking water contamination?

Each of these essential factors is discussed below.

Analytical Methods. Analytical methods must be available such that the presence of the chemicals in water can be validly determined and quantified within acceptable limits. If the level of a contaminant cannot be accurately enough measured to set an RMCL, the contaminant is to be listed. SDWA section 1412(b)(1)(B). This factor is also an important part in determining whether the substance can be regulated (i.e., whether the contaminant can be found in drinking water) and whether an MCL or a treatment technique regulation should be promulgated. The SDWA states that MCLs are appropriate if "it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems." SDWA section 1401. If not, a treatment technique is to be specified.

A number of factors are taken into consideration in evaluating if analytical methods are available, including such factors as:

- Method validity (reliability).
- Sampling techniques and preparation including volume of sample, preservation, and time of transport.
- Laboratory experience/availability/capabilities.
- Precision and accuracy.
- Detection limits.
- Costs of analysis.

The reliability of analytical methods used for compliance monitoring is critical for determining the MCL. The accuracy (lack of bias) and precision (good reproducibility) of the analytical methods is evaluated in order to determine what are reasonable levels of performance by analytical laboratories at levels considered for the MCLs. This evaluation is carried out in order to ensure that reasonable performance expectations for those laboratories which will be performing the actual analysis is considered, instead of an analysis based upon a single, best laboratory situation which is not representative of real world situations.

Health Effects. Consideration of the potential health effects of a chemical encompasses the (1) suitability of the available data for assessing the toxicity of the chemical and (2) the possibility of human health concern from exposure in drinking water. The human health concerns relate to acute and chronic toxicities, carinogenic affects including effects in animals or humans, and other toxicological concerns such as whether or not a contaminant is a mutagen or teratogen. Assessment of these potential health effects also considers the International Agency for Research on Cancer (IARC) criteria and the EPA proposed guidelines for carcinogen risk assessment. In the absence of potential carcinogenic risks, most estimated allowable exposure levels will be considerably higher than usually found in drinking water.

Occurrence in Drinking Water. Consideration of occurrence data encompasses the frequency of occurrence, the level of occurrence and the extent of the population exposed. An examination of the available data with regard to how well it represents national occurrence is carried out, along with an evaluation of the quality of the data.

EPA has conducted a number of national sampling surveys to assess occurrence of certain contaminants in drinking water across the country. In addition, a number of States have conducted surveys of public water systems for certain contaminants. These surveys constitute the best sources of available data on occurrence of contaminants in drinking water. However, limitations of this information for certain contaminants are notable:

- Extent of sampling and sampling sites as being representative of national occurrence.

—EPA surveys conducted to date all have been limited to some extent by resource constraints. The surveys have not been statistically comprehensive such that complete knowledge on the extent of potential contamination is known.

—States are more limited in extent of sampling. While a few States have conducted comprehensive surveys for certain contaminants, most States have not. Reliability of these analytical data is usually unknown.

—Surveys usually are conducted one sample at one time which may not assess reliably the variations in surface water quality or variations in ground water quality due to pumping patterns.

—Also, surveys of ground water systems are seldom of every well in a system and some samples are taken in the distribution systems rather than at the well head.

- surveys analyzed for a limited number of contaminants. For both EPA and State surveys, a targeted list of contaminants is the basis for analysis. Many contaminants thus have not been looked for.
- Reliability of resultant data (quality assurance, limits of detection).

Analysis of SOCs and pesticides requires sophisticated techniques using highly sensitive instruments. The methods used have been developed only recently and quality assurance programs only recently have been a priority concern. Thus, existing data from past surveys may be questioned. In general, if a positive result is reported at a certain concentration, it can be assumed that the contaminant was in the sample but the level could be questioned. However, it cannot be said with confidence that if a sample was negative, the contaminant was not there. Of course, detection limits are also a significant limitation.

The extent and quality of the available data varies for each of the contaminants under consideration. Thus, EPA ususally must base its decision on appropriate regulatory action (or no action) for certain contaminants on an imperfect data set.

In evaluating occurrence data, the most significant aspects are frequency of occurrence and the widespread (or limited) characteristics of the contamination. Because of the limitations in the survey data (noted previously), levels of contamination that have been detected are not believed to be necessarily representative of the quality of drinking water in all supplies across the country. Many of the contaminants in drinking water are man-made synthetic chemicals whose presence in drinking water indicates that a pollution incident has occurred. The levels detected to date may or may not be representative and levels may change due to pollution incidents. Levels for natural contaminants in ground water are generally more representative and would not be expected to change. Thus, because of the imperfect knowledge on the levels of contamination, frequency of occurrence is a more important factor than levels of occurrence in decisionmaking regarding for which contaminant standards should be set. Therefore, data are evaulated for frequency of occurrence, population exposed and the widespread (or limited) nature of contamination problems. A judgment is made for each contaminant based in part upon these factors.

The ideal data base would provide an estimate of the number of public water systems with contamination problems and population exposure and the widespread or limited nature of contamination problems across the country. Where comprehensive data such as these do exist (and human exposure to the contaminant may pose an adverse effect on the health of persons), this is the primary decision factor in determining if a regulation should be set for a certain contaminant. This decision factor is a judgment that

the contaminant occurs in drinking water with sufficient frequency to warrant national regulations. No guidance on what constitutes a sufficient frequency for regulatory action was provided in the SDWA, but frequencies of less than one percent of systems (i.e., less than 500 systems) could certainly be sufficient. Thus, regulations may be appropriate even where the frequency of occurrence was very low if the contamination problem was found in different parts of the country or in various regions of the country.

Potential for Contamination of Drinking Water. For contaminants that have been detected in drinking water but for which data are limited, an analysis of the potential for widespread drinking water contamination is conducted. Factors considered in this analysis in order of importance are the following:

(1) *Occurrence in Drinking Water Other Than Community Water Supplies.* Certain contaminants have been detected in private wells but not in public water systems, usually because of limited sampling programs. For the most part, this factor deals with pesticides which have been detected during certain studies of pesticide usage and drining water contamination.

(2) *Direct or Indirect Additives.* Numerous contaminants are in drinking water as a result of direct addition as a water treatment chemical or indirectly through such actions as leaching from pipe coatings or corrosive actions on piping materials. Pesticides registered for use in or around drinking water fall into this category.

(3) *Ambient Surface Water or Ground Water.* Contaminants detected in surface waters or in ground waters through various water quality surveys or in sampling around hazardous waste sites have the potential for contaminating drinking water.

(4) *Present in Liquid or Solid Waste.* Contaminants known to be in industrial or municipal wastewater effluents or in waste ponds or known to be in solid waste being disposed in landfills have the potential to migrate to drinking water intakes.

(5) *Mobile to Surface Water (run-off) or Ground Water (leaching).* The physical/chemical characteristics of contaminants are examined to determine their potential for movement to a drinking water supply. This is essentially an analysis of the fate and transport of contaminants looking toward the potential for contamination of drinking water sources.

(6) *Widespread Dispersive Use Patterns.* This evaluation assesses the characteristics of the use of a contaminant and the locations of that use that would contribute to potential widespread contamination problems in drinking water.

(7) *Production Rates.* An assessment of the amount of contaminant being produced annually to assess if the potential exists for significant contaimnation.

While the above factors are listed in priority order, the last four factors generally are examined collectively to assess the overall potential for drinking water contamination.

From the list of inorganic, synthetic organic chemicals/pesticides and microbiological contaminants in the October 5, 1983, ANPRM, contaminants have been selected for inclusion in the Revised Regulations. Available data on each of the chemicals on analytical methods, health effects, occurrence and potential occurrence were evaluated using the selection criteria and framework outlined above. Table 1 summarizes the recommended regulatory or non-regulatory action for each contaminant in the ANPRM.

Table 1.—ANPRM IOCs/SOCs/ Pesticides Recommended Actions

Inorganic Chemicals

- Include in Revised Regulations:

Arsenic
Asbestos
Barium
Cadmium
Chromium
Copper
Lead
Mercury
Nitrate
Nitrite
Selenium

- Develop Health Advisories:

Molybdenum
Nickel
Cyanide
Sodium
Sulfate
Silver

- Not included in Revised Regulations, nor is EPA developing Health Advisories at the present time. EPA will evaluate later.

Aluminum
Antimony
Beryllium
Thallium
Vanadium

- Does not currently appear to be a need for an RMCL or Health Advisory. Will examine in future if data warrant reconsideration.

Zinc

Synthetic Organic Chemicals/Pesticides

- Include in Revised Regulations:

Acrylamide
Alachlor
Aldicarb
Carbofuran
Chlordane
cis-1,2-Dichloroethylene
Dibromochloropropane
ortho-Dichlorobenzene
1,2-Dichloropropane
2,4-D
Epichlorohydrin
Ethylbenzene
Ethylene dibromide
Heptachlor
Heptachlor epoxide
Lindane
Methoxychlor
Monochlorobenzene
Polychlorinated biphenyls
Pentachlorophenol
Styrene
Toluene
Toxaphene
trans-1,2-Dichloroethylene
2,4,5-TP
Xylenes

- Develop Health Advisories:

Atrazine
meta-Dischlorobenzene
Dioxin (2,3,7,8-TCDD)
Endrin
Hexachlorobenzene

- Not included in Revised Regulations nor is EPA developing Health Advisories at the present time. EPA will evaluate later.

Adipates
Dalapon
Dibromomethane
Dinoseb
Diquat
Endothall
Glyphosate
Hexachlorocyclopentadiene
Polyaromatic hydrocarbons
Phthalates
Picloram
Simazine
1,1,2-Trichloroethane
Vydate

Microbial Contaminants

- Include in Revised Regulations:

Total coliforms
Turbidity
Giardia
Viruses

- Develop Health Advisory.

Legionella

- Monitoring for Heterotrophic Plate Count will be included within compliance monitoring requirements for total coliforms.

B. Sources of Occurrence and Human Exposure Data

Data on the occurrence of synthetic organic chemicals in air, food and drinking water have been assembled from numerous published reports and supplemented by federal research studies and results from federal and state regulatory activity. The resulting summaries provide a view of potential human exposure indicating the relative exposure of each source of intake. These data are then factored into the determination of the RMCL, as the RMCL must consider intake from all sources, not just from drinking water. Food data, when available, come largely from compliance studies conducted by the U.S. Food and Drug Administration. The market basket studies and compliance program reports provide data on residue levels of selected chemicals in grain and vegetable crops, fish tissue, food animal tissue, spices and other products. FDA total dietary studies for adults, infants and toddlers were used when available. The majority of these data were developed during the 1970's. Data developed by USDA on residue levels in meats were used to supplement existing knowledge as were data from specific studies covering limited areas of the United States.

Data on the level of pesticides in air were developed by the EPA Office of Pesticide Programs and predecessor organizations. Air samples were collected in 1970–72 at sites in 16 U.S. cities and examined for pesticide content. Data on the level of non-pesticide organics in ambient air were extracted from a report for the EPA Office of Air and Radiation (Brodzinsky, R. and Singh, H.B. 1982. Volatile Organic Chemicals in the Atmosphere; An Assessment of Available Data. Prepared by SRI International, Menlo Park, California. Office of Research and Development, U.S. EPA Research Triangle Park, North Carolina. Contract No. 68–02–3452). Data from individual studies were summarized to provide insight to ambient air levels in urban and rural locations. Data on the level of inorganic chemicals in air were extracted from computerized information developed by the EPA Environmental Monitoring and Support Laboratories.

Drinking water data come largely from either (1) National Interim Primary Drinking Water Regulations (NIPDWR) compliance monitoring data, accessed through the Federal Reporting Data System (FRDS), or (2) special studies conducted by EPA's Office of Drinking Water (ODW). Six national surveys have been conducted by ODW since 1975. These include:

- National Organics Reconnaissance Survey (NORS).
- National Organics Monitoring Survey (NOMS).
- National Screening Programs for Organics in Drinking Water (NSP).
- Community Water Supply Survey (CWSS).
- Rural Water Survey (RWS).
- Ground Water Supply Survey (GWSS).

NORS was conducted in 1975 to determine the level of six SOCs in 80 cities across the country. These water supplies served 36 million individuals.

NOMS, conducted in 1976–1977, extended EPA's knowledge on the occurrence of volatile organic compounds in drinking water. One hundred and thirteen cities using surface water were included in this study.

NSP, conducted between June 1977 and March 1981, provided a broadened examination of SOCs in drinking water. The compounds sampled included 23 hydrocarbons, 6 aromatics, 22 pesticides, phenols and acids. One hundred and sixty-six water supplies, mostly using surface water, located in 33 States participated in the study.

Two different CWSS studies have been conducted. The 1969 CWSS provided information on the level of inorganics in drinking water. Over 950 cities throughout the United States participated in the study. A second CWSS was conducted in 1978 providing information on both inorganic and volatile organic contaminants.

The RWS was conducted in 1978 to examine the quality of rural water supplies. The level of both inorganic and volatile organic contaminants was determined for over 800 samples.

The GWSS, focusing on ground water supplies was conducted in 1980–1981. This study provided information on the occurrence of 34 SOCs in nearly 1,000 water supplies.

In addition, the National Inorganics and Radionuclides survey is currently underway and it is anticipated that data from this survey will be available for evaluation before promulgation of the RMCLs proposed herein.

Data on the occurrence of pesticides in drinking water comes from numerous special studies conducted by the EPA Office of Pesticides, U.S. Geological Survey and selected state agencies. Published information on the occurrence of pesticides is integrated into these summaries. Other sources of information include various State surveys and results of monitoring around hazardous waste sites by the Superfund program.

C. Evaluation of Health Effects and Determination of RMCLs

For those contaminants that "may have any adverse effect on the health of persons" (for which analytical methods are available), RMCLs are to be set at a level which:

> no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. Section 1412(b)(1)(i)(B).

Summarized below are the approaches used to determine the RMCLs for non-carcinogens and carcinogens. Additional discussion is provided in the Phase I (Volatile Organic Chemicals) RMCL proposal (See 48 FR 24330).

1. Non-Carcinogens—AADIs

For toxic agents not considered to have carcinogenic potential, "no effect" levels for chronic/lifetime periods of exposure including a margin of safety are referred to commonly as ADIs or Acceptable Daily Intakes. These ADIs are considered to be exposure levels estimated to be without significant risk to humans when received daily over a lifetime.

The intent of a toxicological analysis is to identify the highest no-observed-adverse-effect-level (NOAEL) based upon assessment of available human or animal data (usually from animal experiments). To determine the ADI for regulatory purposes, the NOAEL is divided by (an) appropriate "uncertainty" or "safety" factor(s). This process accommodates for the extrapolation of animal data to the human, for the existence of weak or insufficient data and for individual differences in human sensitivity to toxic agents, among other factors.

ADIs traditionally are reported in mg/kg/day but for RMCL purposes, the "no effect" level needs to be measurable in terms of drinking water quality, i.e., mg/liter. An adjustment of the ADI to mg/liter is accomplished by factoring in an assumed weight of the consumer and the assumed amount of drinking water consumed per day. The "no effect level" in mg/l has been termed the Adjusted ADI (AADI). AADI's are calculated by:

- Determining the highest No-Observed-Adverse Effect Level (NOAEL), or the Lowest-Observed-Adverse Effect Level (LOAEL) in mg/kg body weight/day;
- Dividing by an appropriate safety or uncertainty factor (U.F.);
- Multiplying by the assumed weight of an adult (70 kg); and
- Dividing by the assumed amount of water consumed by an adult per day (2 liters/day).

The formula for this calculation is as follows:

$$AADI = \frac{(\text{NOAEL in mg/kg/day})(70\text{ kg})}{(\text{U.F.})(2\text{ l/day})}$$

In the calculation of the AADIs, the NOAELs are determined based upon data from ingestion studies. If ingestion data are not available, inhalation studies are used and conversion factors applied to convert the exposure. In some cases, however, inhalation will not be used if the data are not determined to be adequate.

The AADIs are calculated based upon the 70 kg adult except for those chemicals where the child has been shown to be the more sensitive subpopulation. In these cases, the AADI is based upon the 10 kg child. Comment is requested on this approach.

In this proposal, AADIs determined from less than lifetime studies are termed provisional AADIs. The AADIs which are based upon lifetime studies will not have the prefix "provisional".

In the proposal, AADIs have been calculated for some chemicals with evidence of carcinogenicity as well as for non-carcinogens. The purpose for calculating AADIs for chemicals with evidence of carcinogenicity is to demonstrate that non-carcinogenic endpoints, as well as carcinogenic endpoints, may occur from exposure to these compounds and these endpoints may be used to identify chronic toxicity levels. However, the derivation of AADIs does not imply that these levels are acceptable for lifetime consumption of the carcinogens. These levels have been derived for the purpose of presenting a broader perspective on the overall toxicity of the chemical.

The uncertainty factor(s) applied in the derivation of the AADI is used in order to estimate the comparable "no effect" level for a large heterogenous human population. In such a population, there may be individuals particularly sensitive to the toxicant and the possibility must be considered that humans are some sensitive to the toxic effects of the chemicals than are animals. The use of uncertainty factor(s) accounts for intra- and inter-species variability, the small number of animals tested compared to the size of the exposed population, sensitive subpopulations and the possibility of synergistic action between chemicals. Uncertainty factors allow for the extrapolation of data to the human population with an added margin of safety to account for the factors discussed above.

The determination of ADIs in the United States began with the examination of food additives. The application of an uncertainty factor of 100 was proposed (Lehman and Fitzhugh, 1954. One Hundred-fold Margin of Safety. Assoc. Food Drug Off. 2 Bull. 18:33–35) as a means of accounting for intra-or inter-species variability to the toxicity of the chemical, sensitive subpopulations within the human population and possible synergism between the intentional and unintentional contaminants in the human diet.

This initial use of the 100-fold uncertainty factor was expanded further in order to better account for the available information. For example, the FDA recommended the use of an uncertainty factor of 1000 instead of 100 in situations where chronic data were unavailable but subchronic data were available in two species. The additional 10-fold uncertainty factor was due to the added uncertainty when estimating an ADI from shorter term toxicity data. The use of a 2000-fold uncertainty factor was recommended by the FDA if subchronic data were available for only one species.

The National Academy of Sciences (*Drinking Water and Health*, 1977. Vol. I) also expanded upon the concept of uncertainty factors by recommending a similar approach when estimating ADIs for contaminants in drinking water. The NAS guidelines are as follows:

- An uncertainty factor of 10 used when good acute or chronic human exposure data are available and supported by acute or chronic data in other species.
- An uncertainty factor of 100 used when good acute or chronic data are available for one species, but human data are not.
- An uncertainty factor of 1000 used when acute or chronic data in all species are limited or incomplete.

The EPA (1980. Guidelines and Methodology used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Quality Criteria. 45 FR 79347) recommended uncertainty factors for estimating ADIs of chemicals in ambient waters. The same guidelines outlined above for the NAS were applied, with the addition of the application of an uncertainty factor of between 1 and 10 when an ADI was estimated from a LOAEL (if a NOAEL was unavailable) in order to adjust the LOAEL into the range of a NOAEL.

The guidelines outlined by the NAS (1977) and further modified by the EPA (1980) for the derivation of the water quality criteria (see Table 2) are used in determining the appropriate uncertainty factor to be applied in the derivation of the AADIs. These guidelines were developed specifically for water contaminants and have had widespread use and are generally accepted in the scientific community. These uncertainty factors have been modified by scientific judgment in instances where more information is known about a specific chemical. As concluded by a member of EPA's Science Advisory Board,

> Safety factors do not pretend to have mathematical precision. When you have very little information, order-of-magnitude safety factors may be about the best you can do in assessing the risk from low levels of exposure. The use of an elaborate mathematical model in such situations may convey a misleading impression of precision. On the other hand, in situations where you do have more information, where there is, for example, a known mechanism for bioaccumulation or enzyme measurements showing how much of the enzyme is being metabolized, then I think it is vital that such information be taken into account in the assessment process. In such situations it would be wrong to ignore the data and to use a simple procedure that mechanically selects a certain power of ten as the appropriate safety factor.

For several of the inorganic chemicals, uncertainty factors have been applied in the derivation of AADIs which differ from the traditional 10, 100 or 1,000 factors. These intermediate uncertainty factors have been applied according to the guidelines (Table 2), when the scientific judgment is that the data appear to fall between categories. These intermediate uncertainty factors may be classified according to the available data and the characteristics of the chemicals. The following is a summary of the data involved which dictated the application of an intermediate uncertainty factor.

- The AADI was based upon a study in which the animals were not exposed for a full lifetime.

The intermediate uncertainty factor was applied to account for the additional uncertainty involving a less-than-lifetime study.

- The chemical is an essential nutrient at low levels and toxic at higher levels.

The application of the traditional uncertainty factor results in a concentration of the chemical being less than that considered necessary for good health. An intermediate uncertainty factor was applied which did not result in the allowable exposure level being below the nutritionally essential level.

- The AADI was based upon a study in which the inorganic chemical was given via food rather than drinking water.

Data suggest that certain chemicals ingested via food may be absorbed less efficiently than via water. Thus, an intermediate uncertainty factor was applied to account for the potential of higher absorption via drinking water.

- The endpoints used to derive the AADI are much more sensitive than the traditional endpoints used in AADI calculations.

An intermediate uncertainty factor was applied which, according to scientific judgment, would provide an adequate margin of safety for the particular chemical.

TABLE 2.—GUIDELINES ON THE USE OF UNCERTAINTY FACTORS

Uncertainty factor	Guideline
10	Uncertainty factor of 10 used with valid experimental results on appropriate durations of exposure in humans.
100	Uncertainty factor of 100 used when human data are not available and extrapolating from valid results of long-term studies in animals.
1,000	Uncertainty factor of 1,000 used when human data are not available and extrapolating from studies in animals of less than chronic exposure.
1–10	Additional uncertainty factor between 1 and 10 when using a LOAEL instead of a NOAEL.
Intermediate uncertainty factor.	Other uncertainty factor used, according to scientific judgment, when justified.

An intermediate uncertainty factor was applied, since the traditional 10-fold uncertainty factor is applied in order to account for sensitive subpopulations within the human population.

Another issue is the rate of absorption of chemicals through the gastrointestinal tract. Numerous factors affect the absorption of a chemical, including the animal used, the presence of other chemicals and bacteria, whether the chemical was administered via food or water and the previous dietary intake. However, the absorption rates of chemicals from the gastrointestinal tract generally have been shown to be comparable in laboratory animals and humans.

The absorption rate assumed for each chemical in the proposal has been determined on a case-by-case basis. The available data, including animal and human studies, were examined for each chemical and a summary of the data is presented in the background Health Effects Criteria Documents. The absorption rate assumed in the AADI calculations was determined using a best estimate based upon the available data.

2. Calculation of the RMCLs

To determine the RMCL, the contribution from other sources of exposure, including air and food should be taken into account. When sufficient data are available on the relative contribution of other sources, the RMCL is determined as follows: RMCL=(AADI)—(contribution from food)—(contribution from air). This calculation assures that the total exposure from drinking water, food and air does not exceed the ADI.

However comprehensive data are usually not available on exposures from air and food. In these cases the RMCL is determined as follows: RMCL=(AADI) (Percentage Drinking Water Contribution).

The percentage drinking water contribution often used in this proposal is a 20 percent contribution for organic chemicals. For inorganic chemicals, the actual contribution from other sources was often available and this data was factored in the RMCL. The NIPDWR used 20 percent as the drinking water exposure factor for pesticides. This exposure factor is judgmental and is adjusted when mitigating information exists. A wide range of environmental exposure distributions occurs across urban and rural populations and differences exist due to age and occupation. Use of a 20 percent contribution is considered to be reasonably conservative and protective. The World Health Organization (WHO), in "Guidelines for Drinking Water Quality" (1984), assigned as little as 1 percent of the ADI to drinking water where the chemical was known to bioaccumulate to a high degree, while greater proportions were assigned where the chemical bioaccumulated to a lesser degree. In "Drinking Water and Health" (1977), the National Academy of Sciences provided projections of 1 percent and 20 percent as illustrations of drinking water contributions.

3. Short-term Assessments

In addition to the RMCLs, short-term risk assessments (health advisories) have been developed for inorganic and organic contaminants for non-carcinogenic endpoints of toxicity. These evaluations are considered to be exposure levels which would not result in adverse health effects over a roughly specified short-time period (usually one-day, ten-days and longer-term (several months to several years)). If data are available for all exposure durations, all three numbers are derived. For certain chemicals, there are inadequate data to derive a specific exposure level. For the chemicals where there are inadequate data to derive a ten-day number, a ten-day number is derived by dividing the one-day number by 10. However, if this number is inconsistent with other levels determined by using data of higher quality, the divided number is not used. If there are inadequate data to derive a longer-term number, a divided number is not used, and a longer-term number is not derived. The longer-term number must be derived from a subchronic study rather than an acute study; only acute and short-term studies are used to calculate the one-day and ten-day numbers.

The toxicological assessment methods used to develop the assessments are the same as outlined for the RMCLs, i.e., the identification of a NOAEL based upon human or animal data and dividing the NOAEL by an appropriate uncertainty factor(s). For RMCLs, a 70 kg adult consuming 2 liters of water per day is used in the calculations to adjust the ADI for drinking water purposes. For these short-term assessments, the 70 kg adult consuming 2 liters of water per day and the 10 kg child consuming 1 liter of water per day are both used to calculate the numbers in terms of the protected population. Both the adult and the child are used in order to provide flexibility for those officials applying the number to use the value that is felt to best fit the needs of the specific situation. Both values are calculated to present a broader perspective than would be available with one number.

The assessments are developed as guidance values for short-term exposure situations, such as spills or accidents, and usually are issued separately by EPA as Health Advisories. They are not assessments which are used to develop RMCLs or MCLs. The purpose of providing the assessments in this proposal is to elicit comment on these scientific assessments which will be then converted into formal Health Advisories. The following is a list of Health Advisories which are available from the National Technical Information Service at the address listed at the beginning of the proposal.

Health Advisories

Acrylamide
Alachlor
Aldicarb
Arsenic

Barium
Benzene
Cadmium
Carbofuran
Carbon tetrachloride
Chlordane
Chlorobenzene (Monochlorobenzene)
Chromium
Cyanide
2,4-D
DBCP
Dichlorobenzenes (o,m,p)
1,2-Dichloroethane
1,1-Dichloroethylene
cis-1,2-Dichloroethylene
trans-1,2-Dichloroethylene
Dichloromethane
Dichloropropane
p-Dioxane
EDB (Ethylene Dibromide)
Endrin
Epichlorohydrin
Ethylbenzene
Ethylene glycol
Heptachlor/Heptachlor epoxide
Hexachlorobenzene
n-Hexane
Lead
Legionella
Lindane
Mercury
Methoxychlor
Methyl ethyl ketone
Nickel
Nitrate/Nitrite
Oxamyl
Polychlorinated biphenyls
Pentachlorophenol
Styrene
TCDD (Dioxin)
Tetrachloroethylene
Toluene
Toxaphene
2,4,5-TP
1,1,1-Trichloroethane
Trichloroethylene
Vinyl chloride
Xylenes

4. Carcinogens

Evaluations of the toxicology of substances which may possess carcinogenic potential is a two-phase process. In the first phase, the toxicological data base for non-carcinogenic endpoints of toxicity was evaluated in the same manner as described above for "non-carcinogens" and AADIs are determined. In the second phase, assessment made of the evidence of the carcinogenic potential (e.g., long-term bioassays in rodents and human epidemiology) as well as information which provides indirect evidence (e.g., mutagenicity and other short-term test results). The objectives of this assessment are (1) to determine the level or strength of evidence that the substance is an animal or human carcinogen, and (2) to provide an upper bound estimate of the possible risks of human exposure to the substances in drinking water.

An issue that is considered in assessing carcinogenicity is inhalation vs. ingestion data. For all chemicals, the total data base is examined, considering data on both ingestion and inhalation exposure. If the data show the chemical to be carcinogenic through ingestion exposure, then the chemical will be considered a potential carcinogen and evaluated based upon the carcinogenicity data.

A second situation consists of instances where the chemical has been shown to be carcinogenic by inhalation exposure but not by ingestion exposure (e.g., negative data exists on exposure by the ingestion route and there is an adequate basis to toxicologically distinguish between the routes of exposure). In these instances the chemical will not be considered a potential carcinogen via drinking water and the RMCL will be based upon non-carcinogenic effects. A third case consists of chemicals which have been demonstrated to have carcinogenic effects via inhalation exposure and the data are either not available or equivocal via ingestion exposure. In these situations, the RMCL will be determined on a case-by-case basis by examining the applicability of the inhalation data to drinking water exposure.

5. Evidence of Carcinogenicity

Several groups of scientists have attempted to classify chemicals on the basis of available evidence for carcinogenicity. These include the IARC, the NAS Safe Drinking Water Committee and EPA via its recently proposed risk assessment guidelines for carcinogenicity (49 FR 46294).

The IARC is responsible for a program on the Evaluation of Carcinogenic Risk of Chemicals to Humans, which involves the preparation and publication of monographs providing a qualitative assessment of the carcinogenic potential of individual chemicals and complex mixtures. The assessments are made by independent, international working groups of experts in cancer research. The program has existed since 1971 and has evaluated over 585 chemicals to date.

Criteria used for evaluating carcinogenic risk to humans were first established in 1971 and were used by the IARC for the preparation of the first 16 volumes of the monographs. These criteria consisted of the terms "sufficient evidence" and limited evidence" of carcinogenicity, referring to the amount of evidence available and not to the potency of the carcinogenic effect.

The later monographs and IARC Supplement 4, used revised criteria to evaluate or reevaluate the chemicals carcinogenic risk to humans. An overall evaluation of carcinogenicity for humans was made on the basis of the combined evidence from humans and experimental systems. The degrees of evidence for carcinogenicity were characterized as follows:

1. Assessment of evidence for carcinogenicity from studies in humans:

(a) Sufficient evidence, which indicates that there is a causal relationship between the agent and human cancer.

(b) Limited evidence, which indicates that a causal interpretation is credible, but that alternative explanation such as chance, bias or confounding, could not be adequately excluded.

(c) Inadequate evidence which indicates that one of three conditions prevailed: (1) there were few pertinent data (2) the available studies, while showing evidence of association, did not exclude chance, bias or confounding (3) studies were available which did not show evidence of carcinogenicity.

2. Assessment of evidence for carcinogenicity from studies in experimental animals:

(a) Sufficient evidence, which indicates that there is an increased incidence of malignant tumors (1) in multiple species or strains or (2) in multiple experiments (preferably with different routes of administration or using different dose levels or (3) to an unusual degree with regard to incidence, site or type of tumor, or age at onset.

(b) Limited evidence, which means that the data suggest a carcinogenic effect but are limited because (1) the studies involve a single species, strain or experiment or (2) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting or (3) the neoplasms produced often occur spontaneously and, in the past, have been difficult to classify as malignant by histological criteria alone (e.g., lung and liver tumors in mice).

(c) Inadequate evidence, which indicates that because of major qualitative or quantitative limitations, the studies cannot be interpreted as showing either the presence or absence of a carcinogenic effect; or that within the limits of the tests used, the chemical is not carcinogenic.

(d) No data, which indicates that data were not available to the Working Group.

The categories sufficient evidence and limited evidence refer only to the strength of the experimental evidence that these

chemicals are carcinogenic and not to the extent of their carcinogenic activity nor to the mechanism involved.

3. Assessment of data from short-term tests:

(a) Sufficient evidence, when there were at least three positive results in at least two of three test systems measuring DNA damage, mutagenicity or chromosomal effects. When two of the positive results were for the same genetic effects, they had to be derived from systems of different biological complexity.

(b) Limited evidence, when there were at least two positive results, either for different endpoints or in systems representing two levels of biological complexity.

(c) Inadequate evidence, when there were generally negative or only one positive test result. Up to two positive test results were considered inadequate if they were accompanied by two or more negative test results.

The IARC then placed the chemicals in one of three groups to reflect carcinogenic risk to humans. These groups are quite broad and are not defined by strict rules concerning the assessment of evidence from the criteria outlined above. The IARC placed the chemicals in the categories based on evaluation of the criteria along with scientific judgment on other properties of the compound which would affect its potential carcinogenic risk to humans. These groups are defined as follows:

Group 1—The chemical, group of chemicals, industrial process or occupational exposure is carcinogenic to humans. This category was used only when there was sufficient evidence from epidemiological studies to support a causal association between the exposure and cancer.

Group 2—The chemical, group of chemicals, industrial process or occupational exposure is probably carcinogenic to humans. This category includes exposures for which, at one extreme, the evidence for human carcinogenicity is almost "sufficient" as well as exposures for which, at the other extreme, it is inadequate. To reflect this range, the category was divided into higher (Group A) and lower (Group B) degrees of evidence. Usually, category 2A was reserved for exposures for which there was at least limited evidence for carcinogenicity to humans. The data from studies in experimental animals played an important role in assigning studies to category 2, and particularly those in Group B, thus, the combination of suifficient evidence in animals and inadequate data in humans usually resulted in a classification of 2B.

In some cases, the Working Group considered that the known chemical properties of a compound and the results from short term tests allowed its transfer from Group 3 to 2B or from Group 2B to 2A.

Group 3—The chemical, group of chemicals, industrial process or occupational exposure cannot be classified as to its carcinogencity to humans.

The EPA has proposed guidelines for carcinogen risk assessment (49 FR 46294) which contain a classification system for chemicals using the degree of evidence of carcinogenicity. The categorization scheme places chemicals into five groups:

Group A: Human carcinogen (sufficient evidence from epidemiological studies)
Group B: Probable human carcinogen
  Group B1: At least limited evidence of carcinogenicity to humans
  Group B2: Usually a combination of sufficient evidence in animals and inadequate data in humans
Group C: Possible human carcinogen (limited evidence of carcinogenicity in animals in the absence of human data)
Group D: Not classified (inadequate animal evidence of carcinogenicity)
Group E: No evidence of carcinogenicity for humans (no evidence of carcinogenicity in at least two adequate animal tests in different species or in both epidemiological and animal studies)

The NAS (*Drinking Water and Health*, 1977, Vol. I) classified chemicals in four categories based upon the strength of the experimental evidence. These categories are: human carcinogens, suspected human carcinogens, animal carcinogens and suspected animal carcinogens.

In the Phase I RMCL proposal, EPA considered three main options for setting RMCLs for carcinogens. These options were: (1) Set the RMCLs at zero, (2) set the RMCLs at the analytical detection limit, and (3) set the RMCLs at a non-zero level based upon a claculated negligible contribution to lifetime risk. In addition, EPA requested comment on the strength of evidence of carcinogenicity and how this could be factored into the RMCL determinations.

RMCLs could be proposed at zero, based upon the inability of scientists to demonstrate experimentally a threshold of effects for "carcinogens". This leads to the assumption that since no threshold dose can be demonstrated for carcinogens, any exposure theoretically would represent some finite level of risk for carcinogens. Depending upon the potency of the specific carcinogen, such a risk could be vanishingly small at very low doses. The House Report which accompanied the Safe Drinking Water Act of 1974, suggested that RMCLs for non-threshold toxicants (i.e., carcinogens) should be zero.

RMCLs could be set at the analytical detection limit. Since RMCLs at zero theoretically are unattainable, basing the levels upon defined state-of-the-art analytical detection limits would provide measurable goals for carcinogens in drinking water. The analytical detection limit is, for all practical purposes, the functional equivalent of zero and thus would present the same philosophy as a zero RMCL.

RMCLs could be set based upon a calculated negligible contribution to lifetime risk using mathematical models which would estimate the number of excess cancer cases occurring in a population as the result of a chemical of specified concentration being present in the drinking water. EPA would select an excess cancer risk level low enough to be considered a "virtually safe" level. Such a level is not really very different from zero and could be argued to fit the requirement that the RMCL be set at the no-effect level with an adequate margin of safety.

EPA has evaluated these three approaches and based upon our analysis and the public comments received on the Phase I proposal, a three-category approach based upon strength of evidence of carcinogenicity will be used to set the RMCLs. This approach is summarized in Table 3. Category I includes those chemicals which have sufficient human or animal evidence of carcinogenicity to warrant their regulation as probable human carcinogens. The RMCLs for Category I chemicals will be proposed at zero. Category II includes those substances for which some limited inconclusive evidence of carcinogenicity exists from animal data. These will not be regulated as human carcinogens. However, RMCLs will reflect the fact that some possible evidence of carcinogenicity in animals exists. Thus, they will be treated more conservatively than Category III substances. Category III includes substances with inadequate or no evidence of carcinogenicity. RMCLs will be calculated based upon AADIs.

Table 3

Three-Category Approach for Setting RMCLs

Category I—Strong evidence of carcinogenicity.
- EPA Group A or Group B
- IARC Group 1, 2A or 2B

Category II—Equivocal evidence of carcinogenicity.
- EPA Group C
- IARC Group 3

Category III—Inadequate or no evidence of carcinogenicity in animals.
- EPA Group D or E
- IARC Group 3

The method for determining the RMCLs for Category II chemicals is more complex than for the other categories. To be placed in Category II, chemicals are not considered to be probable carcinogens via ingestion although some data is available that causes concern. Thus, these substances should be treated more conservatively than Category III "non-carcinogens," yet less conservatively than Category I chemicals. Two options are available for setting the RMCLs for Category II chemicals; the first option involves basing the RMCL upon the AADI which is based upon non-carcinogenic endpoints of toxicity using an uncertainty factor according to the adequacy of the data and toxicological principles. To account for the possible evidence of carcinogenicity, an additional factor would be applied (e.g., AADI divided by a factor of 10 or some other value). A value of 10 is commonly applied for the contaminants proposed for regulation today. Traditionally, for every additional factor contributing to uncertainty, a factor of 10 has been included. Equivocal evidence of carcinogenicity is such an additional uncertainty factor. However, a factor other than 10 will be applied if the properties of the chemical dictate an alternate factor. The second option involves basing the RMCLs upon a lifetime risk calculation in the range of 10^{-5} to 10^{-6} using a conservative method. This risk range is commonly considered to be protective and in the future, if additional data led to reconsideration of a chemical's carcinogenicity, the RMCL would still be set at a level that would represent an extremely low nominal risk. EPA will use both approaches to set the RMCLs for Category II chemicals. The first option, basing the RMCL upon the AADI, will be used if sufficient valid chronic toxicity data are available. If sufficient data are not available, the RMCL will be based upon a risk calculation.

The following is a summary of the classification of the SOCs and IOCs based upon the classification system outlined in EPA's proposed guidelines for carcinogen risk assessment.

IOCs

The classification of the inorganic chemicals for carcinogenicity by the weight of evidence approach in the proposed EPA carcinogen risk assessment guidelines takes into account the total evidence regardless of exposure route (includes inhalation and ingestion exposure). By this approach, asbestos, arsenic and chromium are in Group A (sufficient evidence in humans), nickel and cadmium are in Group B1 (limited evidence in humans), lead is in Group B2 (sufficient evidence in animals), and barium, nitrate/nitrite, sodium, cyanide, copper, mercury, selenium, silver, molybdenum, and sulfates are in Group D (inadequate evidence).

The carcinogenicity data for the inorganic chemicals indicate that the carcinogenic potential from ingestion should be distinguished from that by other routes. Arsenic, in humans, has sufficient evidence for carcinogenicity by inhalation and by the oral route, however other factors such as the potential that it is an essential element were also considered in developing the proposed RMCL. Although lead is technically listed in Group B2, the test dosages that induced cancer in animals were beyond the lethal dose in humans and thus the RMCL for lead will be based upon other sensitive endpoints. Asbestos is a proven carcinogen by inhalation, but the evidence with oral exposure is limited even after extensive studies have been performed. The evidence for the carcinogenicity of chromium, cadmium, and nickel is inadequate by the oral route but sufficient by the inhalation route.

In this proposal, the RMCLs for those chemicals in Group D are set based upon chronic toxicity data (Regulatory Group III). In addition, the RMCLs for chromium, cadmium, arsenic and lead are also being set based upon chronic toxicity data, for the reasons outlined above. The RMCL for asbestos is set based upon an excess risk level (Regulatory Category II) due to the weak oral carcinogenicity data. An RMCL is not proposed for nickel due to problems with the limited toxicological data base, which is now being expanded by new studies.

SOCs

DBCP, dioxin, epichlorohydrin, hexachlorobenzene, alachlor, toxaphene, acrylamide, EDB, chlordane, heptachlor, heptachlor epoxide and PCBs have been classified in EPA's proposed Group B2; sufficient evidence of carcinogenicity in animals.

1,2-Dichloropropane, styrene, monochlorobenzene, and lindane have been classified in EPA's proposed Group C; limited evidence of carcinogenicity in animals.

Pentachlorophenol, cis-1,2-dichloroethylene, trans-1,2-dichloroethylene, o-dichlorobenzene, m-dichlorobenzene, 2,4-D, 2,4,5-TP, ethylbenzene, methoxychlor, toluene, xylene, atrazine, and simazine have been classified in EPA's proposed Group D; inadequate animal evidence of carcinogenicity.

Endrin and carbofuran have been classified in EPA's proposed Group E; no evidence of carcinogenicity for humans.

Table 4 presents a classification of the SOCs and inorganics into the three category approach for setting RMCLs. As noted in the table, there are six chemicals which are classified in Category II (limited evidence of carcinogenicity): styrene, 1,2-dichloropropane, monochlorobenzene, lindane, asbestos and arsenic. Table 4A presents the rationale for the placement of each chemical in its respective category. Table 5 presents the RMCL options for the Category II contaminants. See Section VIII for a further discussion of the RMCLs for the individual chemicals. Comment is requested on the three-category approach for setting RMCLs and on the proposed classifications of chemicals in each category.

TABLE 4.—PRELIMINARY CLASSIFICATION OF SOCs AND INORGANICS INTO THREE CATEGORY APPROACH

Chemical	Category		
	I [1]	II [2]	III [3]
DBCP	X		
Dioxin	X		
Epichlorohydrin	X		
Hexachlorobenzene	X		
Alachlor *	X		
Toxaphene	X		
Acrylamide	X		
EDB	X		
Chlordane *	X		
Heptachlor *	X		
PCBs	X		
Heptachlor epoxide	X		
Lindane		X	
Styrene		X	
1,2-Dichloropropane		X	
Monochlorobenzene		X	
Pentachlorophenol			X
Aldicarb			X
cis-1,2-Dichloroethylene			X
trans-1,2-Dichloroethylene			X
o-Dichlorobenzene			X
m-Dichlorobenzene			X
2,4-D			X
Endrin			X
Ethylbenzene			X
Methoxychlor			X
Toluene			X
2,4,5-TP			X
Xylene			X
Atrazine			X
Simazine			X
Carbofuran			X
All the inorganics except arsenic and asbestos			X
Asbestos (ingestion only, fiber's >10 μm)		X	
Arsenic		X	

[1] Category I—Strong evidence of carcinogenicity; zero RMCL.
[2] Category II—Equivocal evidence of carcinogenicity; RMCL based on cancer risk or the AADI with additional factor.
[3] Category III—Inadequate or no evidence of carcinogenicity, RMCL based on AADI.
[4] Classified by IARC in Group 3. However, re-examination has resulted in the classification in EPA's Group B2 and thus these chemicals have been placed in the "probable" carcinogen category.

TABLE 4A.—CLASSIFICATION OF SOCs AND IOCs BASED ON PROPOSED EPA GUIDELINES

Chemical	EPA classification	Basis
		A. SOCs
DBCP	B2	Carcinogenic in rats/mice. Carcinomas of forestomach in rats and mice of both sexes, positive in short tests.
2,3,7,8-TCDD	B2	Carcinogenic in rats/mice. Cancer in liver, thyroid, tongue, etc. Inadequate evidence in humans.
Epichlorohydrin	B2	Carcinogenic in rats. Cancer in forestomach (oral), subcutaneous injection sites, and nasal turbinates (inhalation). Mutagen. No human evidence.
Hexachlorobenzene	B2	Carcinogenic in rats/hamsters/mice. Liver cancer. No human evidence.
Alachlor	B2	Carcinogenic in rats/mice. Both sexes and dose responsive.
Toxaphene	B2	Do.
Acrylamide	B2	Carcinogenic in two species, tumors at multiple sites.
EDB	B2	Carcinogenic in rats/mice by gavage, inhalation. Dermal in mice only.
Chlordane	B2	Carcinogenic in both sexes of mice. Liver hepatocellular carcinoma.
Heptachlor	B2	Carcinogenic in mice. Liver hepatocellular carcinoma.
Heptachlor Epoxide	B2	Carcinogenic in mice and rats. Hepatocellular carcinoma.
PCB	B2	Certain PCB's carcinogenic in mice and rats (oral). Produces benign and malignant neoplasms.
Lindane	C	Marginal tumors of the liver of both sexes in mice. Carcinogenic metabolite.
1,2 dichloropropane	C	Limited evidence of carcinogenicity in mice. Evidence in rats equivocal (based on NTP draft report).
Styrene	C	Carcinogenic in rats. Alveolar/bronchiolar adenomas and carcinomas in both sexes of rats (oral). However, these studies are not conclusive.
Monochlorobenzene	C	Increased occurrence of neoplastic nodules of the liver in high dose male rats. (Based on NTP draft report).
Pentachlorophenol	D	Negative in studies in rats and mice, mouse data not really solid. Negative for mutagenicity. No human evidence.
Cis and Trans-1,2-dichloroethylene.	D	Not tested.
o-Dichlorobenzene	D	Negative results in both rats and mice NTP (draft report) gavage studies. Some caution should be used since high dose may have been below MTD.
m-Dichlorobenzene	D	Not tested.
2,4-D	D	Inadequate animal data to classify for carcinogenicity.
2,4,5-TP	D	Do.
Ethylbenzene	D	Not tested.
Methoxychlor	D	Inadequate animal evidence. Inconclusive results.
Toluene	D	Negative in one CIIT bioassay (inhalation) up to 300 ppm. MTD was not reached. Negative in microbial bioassay.
Xylene	D	Insufficient information to determine whether or not xylene itself is carcinogenic.
Atrazine	D	Inadequate data to classify.
Simazine	D	Do.
Endrin	E	Negative results in studies, including NCI, 1979, bioassay.
Carbofuran	E	Negative in 2 species and negative in short-term tests.
Aldicarb	E	Negative results in several studies including the NCI bioassay.
		B. IOCs
Asbestos	A	By inhalation, carcinogenic in humans and animals. By ingestion of intermediate (>10 μm length) range chrysotile asbestos, limited evidence in animals-benign polyps in male rats. However, the available epidemiologic/experimental data are inadequate to conclude that the chemical is carcinogenic via ingestion.
Arsenic	A	Carcinogenic in humans by inhalation and ingestion. However, this chemical has potential essential nutrient value.
Chromium	A (based on data for Cr^{+6}).	Carcinogenic in humans by inhalation and rodents by intratracheal instillation. However, regulating as "D" since there is inadequate evidence to conclude that the chemical is carcinogenic via ingestion.
Cadmium	B1	Limited evidence in humans exposed to cadmium fumes, cancer in rats exposed to cadmium chloride aerosol, injection site tumors in animals given cadmium salts. However, regulating as "D" since there is inadequate evidence to conclude that the chemical is carcinogenic via ingestion.
Nickel	B1 (based on subsulfide and carbonyl).	Limited evidence in humans by inhalation, sufficient evidence in animals by inhalation and injection. However, regulating as "D" since there is inadequate evidence to conclude that the chemical is a carcinogenic via ingestion.
Lead	B2	Sufficient evidence in animals. Kidney tumors by oral route in rats. However, insufficient basis to regulate as human carcinogen via ingestion.
Barium	D	Inadequate data to classify.
Nitrate/Nitrite	D	Do.
Sodium	D	Do.
Cyanide	D	Do.
Copper	D	Do.
Selenium	D	Do.
Silver	D	Do.
Molybdenum	D	Do.
Sulfates	D	Do.
Mercury	D	Do.

TABLE 5.—RMCL OPTIONS FOR CATEGORY II CONTAMINANTS

Chemical	AADI with added factor of 10 (μg/l) considering 20 percent drinking water contribution	10^{-5} cancer risk (CAG μg/l)	10^{-6} cancer risk (CAG)(μg/l)
1,2-Dichloropropane	NA	6	0.6
Lindane	0.2	0.26	0.026

TABLE 5.—RMCL OPTIONS FOR CATEGORY II CONTAMINANTS—Continued

Chemical	AADI with added factor of 10 (μg/l) considering 20 percent drinking water contribution	10^{-5} cancer risk (CAG μg/l)	10^{-6} cancer risk (CAG)(μg/l)
Monochlorobenzene	60	24(NAS)	2.4(NAS)
Styrene	140	NA	NA

TABLE 5.—RMCL OPTIONS FOR CATEGORY II CONTAMINANTS—Continued

Chemical	AADI with added factor of 10 (μg/l) considering 20 percent drinking water contribution	10^{-5} cancer risk (CAG μg/l)	10^{-6} cancer risk (CAG)(μg/l)
Asbestos (medium and long fibers)	NA	71,000,000 f/1	7,100,000 f/1

NA = Not available.

VI. Microbiological RMCLs

The Interim Primary Drinking Water Regulations, along with the predecessor U.S. Public Health Service standards, have led to widely improved drinking water quality over the last several decades. Compliance with the regulations for total coliform and turbidity is being achieved by most public water systems. No longer do widespread epidemics of typhoid fever and other waterborne diseases occur in the U.S. population. Yet, waterborne disease outbreaks are at significant levels and the trend in the reported number of outbreaks is increasing. Recognition of waterborne illness is difficult and studies indicate that a relatively small percentage of actual cases is being reported. Some of the outbreaks are caused by fecal agents such as *Salmonella* and *Shigella* whose presence should be indicated by accompanying total coliforms bacteria. Many outbreaks are caused by agents such as *Giardia* and viruses for which total coliform bacteria are inadequate as an indicator. Thus, even though total coliform and turbidity regulations are being met by most systems and the microbiological safety of drinking water has improved greatly over the years, significant problems continue to exist and additional regulatory controls appear necessary.

Because total coliforms and turbidity are satisfactory indicators for a number of organisms which have adverse health effects (pathogens), RMCLs will be proposed for both. In addition, RMCLs will also be proposed for *Giardia* and viruses because they have adverse health effects and their presence is not identified by conventional indicators (e.g., total coliforms). The proposed RMCLs appear in Table 6. As discussed later, an RMCL is not being proposed at this time for heterotrophic bacteria (i.e., standard or hetreotrophic plate count (HPC)) because there are not yet sufficient data to correlate toxicity with HPC and because they are likely to be controlled through the mechanisms for controlling total coliforms and turbidity. In addition, an RMCL is not being proposed for legionellae because the role of public water supplies in the etiology of the disease has not been determined, and because control of legionellae is more effective at locations of susceptible populations.

In addition, EPA is considering proposing a treatment technique regulation which would require: (1) Surface water systems to practice filtration and disinfection and (2) ground water systems to use disinfection. Variances could be issued for systems that can demonstrate that the raw water quality is such that installation of these technologies would not be needed to protect public health or that alternative technologies are at least equally effective. Summaries of the outbreaks of disease, availability of analytical methods, and human health concerns are provided below.

TABLE 6.—PROPOSED RMCLS FOR MICROBIOLOGICAL PARAMETERS

Parameter	Proposed RMCL
Total Coliforms	Zero
Turbidity	0.1 NTU [2]
Giardia [1]	Zero
Viruses [1]	Zero

[1] Analytical methods do exist but they are not considered to be technically and economically available for *Giardia* or viruses for use in compliance monitoring. Thus, a treatment technique regulation will be proposed.
[2] NTU—Nephelometric Turbidity Unit.

A. Interim Regulations and Recent Outbreaks of Waterborne Disease

The Interim Regulations rely on the measurement of total coliforms and turbidity as indicators of water treatment efficiency, deterioration of water quality in the distribution system, and fecal pollution. Applicable to both community and non-community systems, specific MCLs of the Interim Regulations are shown in Table 7.

Monitoring requirements for coliforms depend upon the size of system, and range from 500 samples per month for systems serving more than 4.7 million persons to one sample per month (or per 3 months in some cases) for systems serving 25 to 1000 persons. Turbidity monitoring is required daily for systems using surface water supplies.

From 1971–1983, there were 427 reported outbreaks of waterborne disease in the United States, involving over 106,000 individuals. Forty outbreaks and 21,000 cases occurred in 1983 alone. Many outbreaks, perhaps the great majority, are not reported to the Centers for Disease Control (CDC), which keeps records on the incidence of reportable diseases. This is because only a few types of waterborne diseases are required to be reported and also because disease outbreaks are often not recognized in a community or, if recognized, are not traced to the drinking water source. In Colorado, an EPA–funded effort to improve the outbreak reporting system indicated that only about one-quarter of the actual outbreaks were being recognized and reported. As recognition of waterborne illness has improved, the trend in the reported number (although not necessarily the actual number) of disease outbreaks and cases has increased.

TABLE 7.—INTERIM REGULATIONS: MICROORGANISMS

Parameter	MCL
1. Total Coliforms:	
a. Membrane filter technique:	
Monthly average MCL	1/100 ml.
Single sample MCLs:	
<20 samples/month	<4/100 ml once/month.
≥20 samples/month	4/100 ml in 5 pct of samples.
b. Multiple-tube fermentation procedure (10 ml portions):	
Monthly average MCL	10 pct of tubes.
Single sample MCLs:	
<20 samples/month	3 or more tubes in one sample/mo.
≥20 samples/month	3 or more tubes in 5 pct of samples/mo.
c. Multiple-tube fermentation procedure (100-ml portions):	
Monthly average MCL	60 pct of tubes.
Single sample MCLs:	
<5 samples/month	5 tubes in one sample/mo.
≥5 samples/month	5 tubes in 20 pct of samples/mo.
2. Turbidity:	
Monthly average	1 NTU (up to 5 NTU).
2-consecutive day average	5 NTU.

From 1971–1980, 50 percent of the outbreaks reported were in non-community water systems, 39 percent in community systems, and 11 percent in private systems. Although most of the outbreaks were from non-community systems, about 75 percent of the illness occurred from outbreaks in community systems. Between 1971–1980, the major causes of outbreaks in community water systems were treatment deficiencies (49%) and contamination in the distribution system (32%). Almost all outbreaks (83%) and illnesses (80%) in non-community systems were a result of using ground water without treatment or using ground water with inadequate treatment, primarily interrupted and inadequate disinfection.

Most known agents of waterborne disease cause acute gastrointestinal disorders, especially diarrhea and cramps. During the period 1971–1983, the most commonly identified pathogen was the protozoan *Giardia lamblia*. During these years, there were 77 reported outbreaks of waterborne giardiasis involving nearly 23,000 cases. A number of bacteria also have recently been implicated in waterborne disease. These include *Salmonella* species, *Shigella species, Campylobacter jejuni, Yersinia enterocolitica*, and enteropathogenic *E. coli*. Viral agents implicated in recent waterborne illnesses include Norwalk and Norwalk-like agents, rotaviruses, and the hepatitis A agent. In about half the waterborne outbreaks the causative

agent has not been found. There is growing suspicion that many of these may be due to viruses. Unfortunately, the unavailability of suitable analytical techniques have impaired efforts to resolve this issue.

B. Total Coliform Bacteria

Total coliform bacteria have been used for decades as the primary measurement of the microbiological quality of drinking water. Total coliform bacteria are a measure of the efficiency of water treatment, disclose deterioration in the distribution system and signal the possible presence of fecal contamination. Analytical methodology for total coliform monitoring has existed for decades. Current EPA drinking water regulations specify the use of either the multiple-tube fermentation technique or the membrane filter technique. Both enjoy widespread acceptance and are recognized as suitable methods by *Standard Methods for the Examination of Water and Wastewater.* EPA is also considering additional analytical methods, such as Clark's Presence-Absence test (see *Standard Methods*, 6th ed.) which detects coliforms but does not quantify them.

Coliforms are usually present in fecally-polluted water and are often associated with disease outbreaks. Although coliforms are not usually pathogenic themselves, their presence in drinking water indicates the likely presence of pathogens (e.g., *Salmonella* and *Shigella*). However, use of total coliforms has a number of drawbacks including the following:

- Given their ubiquitous nature, coliforms are often found in the absence of fecal contamination.
- There are reports of pathogen occurrence and disease outbreaks where coliforms were not detected.
- Coliforms are inadequate for predicting the presence of pathogens/toxins not associated with fecal contamination such as atypical mycobacteria, *Legionella*, and algal toxins.
- They also may not adequately predict the presence of enteric viruses, *Giardia* and some other organisms, because they are less resistant to treatment (e.g., disinfection) than these organisms.

The qualitative use of total coliforms can be scientifically justified, but there is an absence of scientific data in the literature supporting a particular value for coliform density, below which the water can be considered safe. Pathogens and outbreaks have been associated with coliform densities ranging from zero to very high levels. This is not surprising: pathogens vary in their: (1) Association with fecal contamination, (2) die-off times in water, and (3) resistance to disinfection or other treatment. Although the total coliform indicator is an inexact tool, fecal pathogens in ambient water are usually accompanied by substantially higher levels of total coliforms. Since higher levels of pathogens should roughly translate to greater risk of disease, coliform densities indirectly serve as a measure of the risk of waterborne disease. Treatment which provides coliform-free water as measured by the standard tests should reduce pathogens to minimal levels, even though large volume risk-free water is probably unattainable.

Despite these and other limitations, total coliforms are still the single most useful indicator of drinking water quality. Because total coliforms most directly measure pathogens which widely occur in drinking water, EPA is proposing an RMCL for total coliforms. (To assure a safe drinking water supply, control of total coliforms should be used in combination with other microbiological parameters and protective measures, e.g., turbidity, filtration and disinfection.) The discontinuance of total coliforms as an indicator of treatment efficiency would substantially undermine the ability to predict the potential presence of pathogens, even if turbidity monitoring is retained. Turbidity removals, for example, cannot measure disinfection effectiveness.

The object of an RMCL for total coliforms is to recommend that as a goal the consumer will not be exposed to a sufficient dose of a pathogen to result in disease. Since the relationship between coliform and pathogen levels is highly variable, the proposed RMCL for total coliforms should be zero, i.e., no detectable coliforms/100 ml as measured by the Most Probable Number (MPN), Membrane Filter (MF), and other EPA approved analytical methods in order to assure maximum protection within the limits of the measurement technique. This RMCL includes an adequate margin of safety. While the RMCL is being proposed at zero, the concept of "presence-absence" is being considered as the basis for the enforceable MCLs. This would involve measurement of total coliforms to determine only if coliforms were present or absent without quantification. For example, MCL regulations could specify that 95 percent of samples examined over a given time period have no coliforms present. Public comment is requested on setting an RMCL of zero for total coliforms and on the use of the Presence-Absence concept as the basis of the total coliform MCL.

C. Turbidity

Turbidity in water is a non-specific measure of suspended material in drinking water and is measured by determining the degree of light scattering caused by particulates in a sample. Turbidity has been used for decades as an indicator of drinking water quality indicating the presence of such particulates as clay, silt, finely divided organic and inorganic matter, and microorganisms. Analytical methodology for turbidity monitoring is available. Currently, the only EPA-approved technique is the Nephelometric Method. This is also recognized as an acceptable technique by *Standard Methods for the Examination of Water and Wastewater.*

Turbidity is an imprecise measure because particulate characteristics vary from system to system and seasonally within the same system, and some particulate types are more significant than others for human health. The more important particulates appear to be larger than 0.03 μm in diameter and are usually organic materials. Turbidity is of concern in drinking water because of the following characteristics:

- Turbidity can reduce the efficiency of disinfection.

—Certain particles protect adsorbed pathogenic organisms against disinfection. In general, inorganic particles such as clays and water flocculating agents appear to have little, if any, protective effect. In contrast, organic particulate matter, whether cell debris, sewage solids, or living or dead organisms such as nematodes or crustaceans, can provide marked protection to microorganisms associated with them.

—A significant disinfectant demand can chemically interfere with disinfection during treatment or maintenance of a disinfectant residual in the distribution system.

- The turbidity can be caused by particles that are toxic themselves or that adsorb toxic inorganic or organic substances from the water.
- Higher turbidity levels can also interfere with total coliform analyses by the membrane filtration procedure.
- Turbidity is a measure of the efficiency of drinking water coagulation and filtration processes. Removal of turbidity usually provides concommitant removal of microbial pathogens, especially those which aggregate on particulates, as well as particulate

matter which is either toxic itself or adsorbs toxic contaminants.

Thus, turbidity represents many concerns in drinking water quality but distinct relationships between levels of turbidity and the safety of the drinking water are not quantifiable. However, as a standard sanitation principle, the lower the turbidity of treated water, the less likely the water will contain contaminants deleterious to human health. For this reason and because turbidity is common in drinking water sources, EPA is proposing an RMCL for turbidity.

As with the total coliform RMCL, the object of the turbidity RMCL is to provide maximum assurance that the consumer will not be exposed to a sufficient pathogen dose to result in disease (including a margin of safety). On this basis, the proposed health goal for turbidity is 0.1 NTU. This is primarily based upon the premise that the lower the turbidity levels, the less the probability that aggregated microorganisms are entering finished drinking water. Significantly, there appears to be some correlation between turbidity removal and *Giardia* removal efficiencies in filtered water. Setting the RMCL at 0.1 NTU represents the lowest level for which sufficient data are available (and is essentially the analytical level of detection). Lower turbidity can be measured, but only through careful measurements under controlled conditions. An RMCL for turbidity of zero would not be appropriate since even distilled water has turbidity of about 0.05 NTU. In addition, additional benefits of achieving very low turbidities include the following:

- Several studies have demonstrated very substantial removal of *Giardia* cysts by coagulation and rapid granular media filtration. However, this would not suggest that a drinking water with a low turbidity level would de facto be safe from *Giardia*. *Giardia* can be present in low turbidity unfiltered waters.
- Removal of turbidity particles for cyst removal will also substantially reduce levels of other pathogenic organisms and toxic particulate matter, such as bacteria, pathogenic viruses and protozoan cysts.
- The total coliform group, while the single best indicator of water quality, is inadequate by itself to measure drinking water quality. The measurement of turbidity complements coliform monitoring since particles may interfere with coliform analysis and particles may chelate toxic materials even in the absence of coliforms. There are cases on record where outbreaks were accompanied by sudden rises of turbidity in filtered coliform-free water. In addition, turbidity is monitored at least daily and results are available in a much shorter time than for coliforms.

Other organizations support turbidity controls including the American Water Works Association (AWWA) and the World Health Organization (WHO).

- The AWWA policy is as follows.

> Today's consumer expects a sparkling, clear water. The goal of less than 0.1 unit of turbidity insures satisfaction in this respect. There is evidence that freedom from disease organisms is associated with freedom from turbidity, and that complete freedom from taste and odor requires no less than such clarity. Improved technology in the modern treatment processes make this a completely practical goal.

The WHO guidelines for turbidity state that "turbidity must always be low, preferrably below 1 NTU and always less than 5 NTU."

Public comments are requested on setting an RMCL for turbidity in drinking water. Specifically:

- Is a level of 0.1 NTU appropriate for the RMCL? If not, what other level and upon what basis?

D. Giardia

The protozoan *Giardia lamblia* causes more waterborne disease outbreaks in the United States than any other single identified etiologic agent. Symptoms of giardiasis include diarrhea, fatigue, abdominal cramps, and possibly other gastrointestinal symptoms, and these may persist for several days to several months. For these reasons, EPA is proposing an RMCL for *Giardia*.

Between 1971–1983, there were 77 reported outbreaks of waterborne giardiasis with nearly 23,000 cases. The trend in outbreaks has been on the increase, probably due to greater recognition and reporting of giardiasis outbreaks in recent years. Waterborne giardiasis represented 15.7 percent of the total reported cases of giardiasis in 1980 and 2.4 percent in 1981. These percentages, however, may substantially under-represent the actual situation, since the route of transmission for many cases is unknown and may in fact be waterborne. In Pennsylvania recently, there were four separate out breaks of waterborne giardiasis, with about 700 cases. Over 350,000 individuals were being served by public water systems under boil water orders (i.e., water provided by a public water system is not safe to drink unless boiled first). In three outbreaks, the systems provided only chlorination. In the remaining outbreak, coagulation, filtration and disinfection were used, but the system appeared to be overloaded and improperly operated. In all four situations, the systems were in compliance with total coliform and turbidity MCLs.

The populations most at risk are those consuming surface waters which are either untreated or only chlorinated. *Giardia* are effectively controlled by filtration (including coagulation) and disinfection. Disinfection alone is not normally sufficient. It is estimated that over 65 million people are served by surface water systems that either provide only disinfection or no treatment at all.

Cyst recovery and analysis procedures have been published in the literature, but they are considered insensitive, tedious and expensive. The most commonly used method for recoverl and detection of *Giardia* from water was developed by EPA. This involves filtering large volumes (up to 2,000 liters) of water through an Orlon fiber filter, separating the cysts from the fiber, and examining the cyst concentrate microscopically. This procedure appears in *Standard Methods for the Examination of Water and Wastewater* (15th ed.), as a tentative method. Beyond the difficulties in recovery and detection, it is not yet possible to distinguish between viable and non-viable cysts. This method is therefore not considered available for the monitoring of waterborne *Giardia*. Promising research is being conducted on *Giardia* recovery and analysis techniques.

The proposed RMCL is based upon a human study. In this investigation, male volunteers were fed human-source *Giardia* cysts contained in gelatin capsules. Those receiving one cyst were not infected, while infections did occur in the group receiving ten cysts. A major deficiency of this study is that cyst viability was not established; thus it is possible that a sizable fraction of the ingested cysts were non-viable. In addition, only two individuals were tested at the ten cyst level (both, however, were infected). Recent unpublished data with mice support the low infective dose for *Giardia*. In four experiments, the average dose at which 50 percent of the animals were infected (ID_{50}) were 1.4, 2.6, 3.8 and 17.6 cysts. Since some of these cysts may have been non-viable, the ID_{50} dose may actually be lower than the results indicate.

On the basis of these studies and inclusion of a safety factor, the RMCL is proposed at zero viable cysts. Because of the insensitivity of the currently available analytical procedures, the potential for intermittent contamination

and thus difficulty in monitoring, and lack of technologically and economically feasible methods, treatment requirements are being considered (instead of setting an MCL). However, the inability to measure these contaminants alone does not prevent establishment of an RMCL. In this case, it is reasonably clear that any *Giardia lamblia* cyst can have an adverse health effect. Therefore EPA is setting an RMCL of zero. Treatment techniques could include filtration and disinfection for all water systems using surface water. Ground water is not nearly as vulnerable to cyst penetration since the aquifer and the overlying soil usually serve as an effective barrier. Thus, filtration of ground water will not be proposed. Variances under section 1415 may be considered in those circumstances where the system is able to demonstrate to the State by a sanitary survey or other means to be specified, that the treatment is not needed to protect the health of persons because of the quality of the raw water. The treatment technique requirements will be proposed when the MCL for other contaminants are proposed. Criteria for determining if a variance would be appropriate will be included in the proposal.

Public comments are requested on this approach of setting an RMCL of zero for *Giardia* and treatment requirements to control *Giardia* in drinking water. Specific comments are also requested on the following:

- Are analytical methods available (i.e., is it economically and technologically feasible) to ascertain the level of *Giardia* in drinking water?
- What specific criteria should be included in the regulations that would allow States to evaluate if a variance should be issued to a particular system?

E. Pathogenic Viruses

Between 1978–1982, there were 18 reported waterborne disease outbreaks in the U.S. caused by viruses, with over 5,700 cases. These values are probably far too low to represent the actual number of outbreaks because there is evidence that most of the waterborne disease outbreaks of unknown origin are caused by viruses. Viruses are a class of infectious agents which are extremely small (smaller than bacteria) and reproduce only within cells of a suitable living host such as humans. They contain genetic material surrounded by a protein coat. Pathogenic viruses, by definition, are those that adversely affect health. The lack of adequate tools for the recovery and analysis of most pathogenic waterborne viruses undoubtedly contributes to this under-reporting.

The most important of the waterborne pathogenic viruses are the Norwalk and Norwalk-like agents, rotavirus, and the hepatitis A agent. Except for the latter, their predominant health effect is acute gastroenteritis. Hepatitis A agent results in hepatitis. All have been implicated in recent waterborne disease outbreaks. While serological techniques are available for identifying these agents (e.g., radioimuno-assay, immune electron microscopy, and others), there are no satisfactory culture procedures currently available. Promising research on culturing rotaviruses and hepatitis A agent is presently being conducted.

The classical enteroviruses (poliovirus, echovirus, and coxsackievirus) are common in ambient water and are occasionally found in drinking water, but they have not been implicated in recent outbreaks. Nevertheless, their health effects may be severe (e.g., meningitis, paralysis, myocarditis, diarrhea).

Unlike many of the other agents, recovery and analysis procedures for these enteroviruses do exist, some of which are described in *Standard Methods for the Examination of Water and Wastewater* (15th ed). Viral assay, however, is beyond the capability of most water microbiology laboratories and must be done by a trained virologist working in specifically equipped viral laboratory facilities.

The minimum infective dose for some strains of waterborne viruses is very low. There is evidence that in some instances, as little as one tissue culture infective dose is able to infect a person. Data from a recent study where healthy human volunteers were infected by Echovirus 12 suggest that 1 percent of a population could be infected by 17 plague-forming units of this virus. Because of this, the goal should be to have no viruses in potable water. This is supported by the WHO. Thus, the proposed RMCL goal for human pathogenic viruses in drinking water is zero. This RMCL goal would include the enteroviruses in addition to any others for which analytical methods are not yet available. Because EPA concludes that one virus may have adverse effects, it is able to propose an RMCL, despite the fact that the measurement is difficult.

Because routine, validated procedures for detection of the most important waterborne viruses (hepatitis A agent, rotaviruses, and Norwalk and Norwalk-like agents) are not yet technically feasible, and because of the potential for intermittent contamination which presents difficulties in effective monitoring, a treatment technique requirement is being considered for proposal in the next rulemaking. This could include coagulation, filtration and disinfection for water systems using surface water and disinfection for systems using ground water. Alternatively, an easily measurable surrogate for waterborne viral pathogens could be selected as the proper regulatory approach; however, the only techniques currently under study are classical enteroviruses and coliphage and these are not considered sufficient to provide protection against the myriad of pathogens potentially present in various drinking waters. A variance could be considered in those circumstances where a system is able to demonstrate to the satisfaction of the State, by an on-site sanitary survey and other means to be specified, that treatment would not be needed to protect public health because of the quality of the raw water supply. The treatment technique requirements, if any, will be proposed when the MCL for other contaminants are proposed. Criteria to be used by public water systems and States in determining if a variance would be appropriate will be included in the proposal.

Public comments are requested on this approach of setting an RMCL of zero for viruses and setting treatment requirements for control of viruses in drinking water. Comments are also requested on the following:

- Are analytical methods available (i.e., is it economically and technologically feasible) to ascertain the level of pathogenic viruses in drinking water?
- What specific criteria should be specified in the regulations that would allow States to provide variances to certain systems?
- Are satisfactory methods available for recovery and analysis of classical enteroviruses or coliphage and are they representative surrogates for pathogenic viruses? If so, should an RMCL and MCL or a treatment technique be established for classical enteroviruses or coliphage?

F. Legionellae

Legionellae are bacteria that have been identified as the cause of legionellosis. It has been estimated that 50,000–100,000 cases of this disease occur annually within the United States, and are caused primarily by 1 of the 26 currently recognized species of the genus *Legionella*. The number of cases attributable to drinking water is unknown. Most people who have developed Legionnaires Disease, the pneumonia form of legionellosis, were

patients that were immunosuppressed, or were individuals who appeared to be more susceptible because of an underlying illness, heavy smoking, alcoholism, or were over 50 years old. In contrast, while some apparently healthy individuals have developed Legionnaries Disease, outbreaks involving healthy people have been limited mostly to the milder non-pneumonia form of the disease called Pontiac Fever.

Legionellae are abundant in ambient water, and may survive water treatment, especially since they are relatively resistant to chlorine. Even conventional treatment (i.e., filtration and disinfection) probably cannot prevent the passage of a small number of legionellae into the distribution system. They may also be introduced into drinking water via broken or corroded piping, repair of existing mains, installation of new mains, back siphonage, and cross connections. When the legionellae enter hot water tanks, they can settle to the botom and, under certain circumstances, will proliferate. If they proliferate, plumbing fixtures such as aerators, water fitings, and showerheads may be seeded, resulting in colonization and growth at these sites. They are often found in the hot water plumbing of hospitals, hotels, and other buildings, especially in hot water tanks and showerheads where the hot water temperature does not exceed 120°F. In many hospitals, the hot water temperature is maintained at this temperature and below to prevent patient scalding and to reduce energy costs.

There is good epidemiologic evidence from several hospitals that Legionnaires Disease is transmitted by aerosols of potable water from showerheads containing legionellae. Other sources implicated in disease transmission are aerosols from cooling towers and whirlpools. Inhalation of aerosolized potable water is probably the primary route of infection, although ingestion is a possibility.

Analytical tools exist for recovery and enumeration of these organisms from plumbing systems. However, these are not yet very efficient for selectively recovering and enumerating legionellae from drinking water.

Because of the ubiquity of legionellae in ambient water, their proliferation primarily at warmer temperatures, their relative resistance to chlorination and ability to colonize in plumbing systems, control is probably more appropriate at locations where susceptible populations reside, rather than at the waterworks. More significant, however, is the fact that virulence factors have not yet been identified for the organisms in this genus. There is great variation in virulence, and the mere presence of large populations of legionellae in the drinking water does not necessarily represent a health threat. For all these reasons, setting national drinking water regulations for legionellae appears to be inappropriate at this time, and an RMCL is not being proposed.

EPA has prepared guidance for hospitals and other high risk locales; this guidance is summarized below and is available from EPA at the address cited at the beginning of this notice. In order to reduce legionellae levels in drinking water, storage reservoirs should be managed to minimize the addition of organic matter and growth of algae and protoza. Moreover, newly repaired or constructed components of the water distribution system must be thoroughly flushed and disinfected before being put into operation. Even after flushing and disinfection, one cannot assume legionellae have been controlled since design factors in the distribution system may impede the efficiency of these measures.

In order to control legionellae growth in hot water plumbing, several approaches may be considered. Most of the published data have examined the effectiveness of chlorine and/or heat. The maintenance of free chlorine has been found effective for controlling legionallae. Shock chlorination is also effective, but unless free chlorine is maintained within a system, the organism may reappear. Control can probably be achieved if free chlorine levels in the hot water are maintained above 2 mg/l, but at these levels corrosion of pipes may occur. Successful eradication has been reported with 3 mg/l chlorine in the hot water system for 10 days, followed by a 1.5 mg/l maintenance level. With this treatment, only a slight increase in corrosivity was found. Undoubtedly, the level of chlorine found effective will depend, in part, on the design criteria of the plumbing system. A pertinent facet in controlling legionellae is the difficulty of maintaining a chlorine residual in hot water. This problem can be minimized by using either a closed recirculating system or a continuous-flow proportional chlorinator on the hot water system.

Heat shock (160 °F for 1 hour) may eradicate legionellae in hot water tanks and is a temporary measure which must be carried out routinely to be effective. Maintenance of hot water at 130 °F or higher apparently controls the organism, while lower temperatures may not. If legionellae are controlled by heat, care must be taken to prevent scalding, especially in health care situations.

Legionellae may be controlled by ultraviolet radiation. Data on ozone treatment are incomplete at this time.

In addition to disinfection and heat, other procedures may be effective in controlling legionellae. Hot water tanks should be designed to give uniform temperatures throughout. Dead-end piping should be eliminated. Hot or cold water tanks used intermittently should be disconnected from the system, drained, flushed, and disinfected before being reconnected. Hot water tanks should be drained regularly or at least be bled to remove accumulated sludge that may serve as a substrate for growth of legionellae and other micro-organisms. Taps and showers in unused areas of health care facilities should at least be flushed before patients are exposed to them. Finally, faucet sieves and aerators, and rubber washers and gaskets in the plumbing system should be used with caution, especially in institutions housing compromised individuals and where hot water is maintained at temperatures lower than 130 °F.

Public comments are requested on whether it is appropriate to propose an RMCL and primary drinking water regulations for legionellae or whether the appropriate action is to provide guidance.

G. Heterotrophic Bacteria

Heterotrophic bacteria are those which use organic nutrients for growth. This group includes virtually all of the bacterial pathogens as well as many other innocuous bacteria. The population density of these bacteria in water is often measured by the Standard Plate Count (SPC) procedure, as described in *Standard Methods for the Examination of Water and Wastewater*. The 16th edition of this book changes the SPC designation to Heterotrophic Plate Count (HPC).

Primary reasons for considering a regulation for heterotrophic bacteria include the following:

- Many heterotrophs in water are opportunistic pathogens (30% in one study). There is some evidence that numerous hospital-acquired infections have been caused by waterborne opportunistic pathogens. Thus, a higher bacterial density, as measured by the HPC procedure, may reflect a higher level of pathogens in the water which are able to cause disease in the compromised population.
- High HPC densities, or sudden increases of HPC density, may indicate water quality deterioration. Thus, this

group or organisms can be used to provide warning of a filter bed breakthrough, monitor the effectiveness of disinfection throughout the distribution system provide a method for monitoring the condition of point-of-use water filters and provide other monitoring data. In some of these areas, HPC monitoring can be more informative than total coliform monitoring. For example, in research studies of point-of-use filters, coliforms are rarely found in the effluents. The growth or potential growth of opportunistic pathogens or even primary pathogens could be better signalled by higher HPC densities in the effluent. Thus, HPC monitoring can be a useful supplement to coliform monitoring.

- The NAS stated that HPC is a valuable procedure for assessing the bacterial quality of water, and that a density less than 500/ml is attainable by water systems (*Drinking Water and Health*, 1977, Vol. I).
- Higher HPC densities may interfere with total coliform analysis. Several published articles have indicated that non-coliform bacterial densities greater than 500 colonies/ml can suppress coliform growth with both the membrane filter and multiple tube fermentation procedures. There is also strong evidence that drinking water samples containing high non-coliform bacterial densities resulting from regrowth during sample transit may reduce the chances of detecting total coliforms.

Although there is some evidence that high heterotrophic bacterial densities are of concern, the Agency believes that it would be premature to propose an RMCL, given the lack of conclusive data regarding the link between opportunistic pathogens in drinking water and nosocomial (hospital-acquired) infections. Instead of proposing an RMCL, MCL and monitoring/reporting requirements, the Agency is considering incorporating a level of HPC control into the total coliform monitoring requirements since high densities of HPC interfere with coliform analysis. The monitoring requirements for total coliforms could specify that a certain percentage of the samples collected for coliform analyses would also be analyzed for HPC; if HPC were greater than some level (e.g., 500 colonies/ml), the total coliform analyses would not be valid. This would provide a measure of quality assurance not previously required in the Interim Regulations. Monitoring for HPC would also indicate treatment effectiveness and possible deterioration of water quality.

Public comments are requested on the following:

- Should an RMCL and MCL be set for HPC? Upon what basis and what level?
- Should HPC be included in the monitoring requirements for total coliforms such that HPC could not exceed a certain density in order to have valid total coliform results? What level would be appropriate?

H. Treatment Technique Requirements

Discussed below are possible treatment regulations that EPA is considering for the next rulemaking. The regulations are not being proposed at the present time and are presented for the purpose of public comment.

1. Mandatory Filtration and Disinfection of Surface Water for Microorganism

EPA is considering a regulation requiring the filtration and disinfection of all surface waters before distribution to consumers. This regulation would provide protection against a myriad of disease-producing microorganisms which can frequently be found in ambient water used as drinking water supplies. As discussed previously, a search in finished drinking water for each of these primary and opportunistic pathogens would not be technologically or economically feasible. The concentration of pathogens in water would usually be sufficiently small so as to require large-volume samples. Many are so fastidious that only highly specialized laboratory techniques can be used to recover and detect them, if they can be detected at all. This is true of the hepatitis A agent, rotavirus, Norwalk and Norwalk-like agents, and *Giardia*. Unfortunately, total coliform bacteria are inadequate as an indicator for the presence of these organisms. Thus, EPA may propose a treatment requirement in the next rulemaking.

Of the approximately 14,000 community water systems in the U.S. which use surface water, about 79 percent practice full conventional treatment and about 96 percent employ at least disinfection. Between 1971 and 1980, there were 19 reported waterborne disease outbreaks with over 11,000 cases in localities served by surface waters receiving chlorination only. This represented 35 percent of the total number of outbreaks and 44 percent of the cases associated with surface water supplies, even though disinfected-only surface water systems represent less than 17 percent of the total number of surface water systems. During that same period, 6 disease outbreaks (11% of the total) and over 200 cases were associated with untreated surface water supplies. These data strongly suggest that filtration and disinfection of surface waters substantially reduces the potential for waterborne disease outbreaks. As previously discussed, recent studies suggest that actual disease outbreaks may be much higher than reported.

Rapid granular filtration, in use since the 1890s, can remove between 90–99.9 percent of the bacteria and protozoan cysts and 90–99 percent of the viruses from source water. Slow sand filtration, in continual use from the early 19th century, can remove 90–99.9 percent of the bacteria, and viruses and 90–99 percent of protozoan cysts. A third type of filter, diatomaceous earth (diatomite), used since World War II, can remove 90–99 percent of the bacteria, 95 percent of the viruses, and 99 percent of the cysts. Percentage removals for filtration without pretreatment (i.e., coagulation, flocculation, and settling) are extremely variable, ranging from 0–90 percent for bacteria and cysts and 0–50 percent for viruses.

Besides providing a barrier to organisms, especially for *Giardia*, viruses, and other pathogens relatively resistant to disinfection, filtration reduces the level of particulate matter that may protect microorganisms from disinfectants, reduces the level of toxic particulate matter, and reduces short-term fluctuations in water quality. Formation of trihalomethanes and other by-products of disinfection are also reduced by filtration which reduces the quantity of precursors that can react with the disinfectant.

Filtration and disinfection reduce contamination continuously and deal with the possible events of periodic contamination. Without treatment, monitoring for contamination is necessarily intermittent and the microbiological quality of the drinking water is not known for more than a day or more and sometimes much longer. This is especially true of small systems where total coliform monitoring is quite limited. In 1982, about 24 percent of the public water systems violated coliform monitoring requirements at least intermittently and 14 percent violated turbidity monitoring requirements. Furthermore, as noted previously, total coliform monitoring is not a adequate indicator of all possible pathogens.

Any filtration and disinfection of surface supplies would not necessarily require all systems to adapt these treatment methods. The SDWA (section 1415) allows systems to receive a variance from the requirements if certain conditions are met. All systems would be required to install filtration and disinfection unless the system demonstrates to the satisfaction of the

State that the treatment technique is not necessary to protect the health of persons because of the quality of the raw water source of the system. Criteria would be provided in the regulation which the system must meet in order to receive a variance.

The practice of filtering surface water is supported by a number of professional groups such as the AWWA: "The American Water Works Association (AWWA) strongly supports the practices of filtration of surface water used as sources of public water supply, disinfection of public water supplies, including the maintenance of residual disinfection in the distribution system, ..." (AWWA, 1983. AWWA Officers and Committee Directory, Policy Statements and Official Documents, p. 74). In addition, a workshop convened by the EPA's Office of Drinking Water, in conjunction with the American Society for Microbiology, to advise EPA on a variety of drinking water issues, strongly recommended the filtration of surface waters (Assessment of Microbiology and Turbidity Standards for Drinking Water, Dec. 2–4, 1981, July 1983, EPA 570–9–83–001).

Public comment is requested on the following:

- Should a treatment technique requirement be established such that system using surface waters would be required to use filtration and disinfection? Upon what basis?
- What specific filtration and disinfection technologies should be included in the definition of a "filtration" and "disinfection"? For example, direct filtration? slow sand filtration?
- Should these treatment requirements apply to non-community drinking water systems?
- What criteria should be specified that would provide guidance in the issuance of variances?

2. Mandatory Disinfection of Ground Water

EPA may also propose, in the next rulemaking, a treatment regulation requiring the disinfection of all ground waters before distribution to the consumer. Many of the same microorganisms that occur in surface waters are also found in ground waters. Because a search for each pathogen is not technically or economically feasible, and because the presence of some are not adequately signalled by the presence of coliforms, a treatment technique regulation may be proposed. Filtration of ground water supplies, while encouraged, may not be proposed as a requirement because the soil acts as a natural filter, thereby usually reducing microbial and particulate contamination of the underlying water.

The number of reported disease outbreaks and cases associated with untreated ground water supplies are substantially greater than those for treated ground water supplies. According to published data, communities served by untreated ground water have had 3.7 times as many cases of illnesses. Between 1971–1982, untreated well water was associated with 110 disease outbreaks and over 8500 cases of illnesses. If untreated spring water is added to this total, the values are 126 outbreaks and over 9800 cases. In 1982, untreated ground water was responsible for 28 percent of all reported waterborne disease outbreaks and 10 percent of all waterborne illnesses. The etiological agents implicated in these outbreaks were the hepatitis A agent, *Yersinia*, and *Giardia;* in 5 outbreaks the agent was not identified.

Adequate disinfection reduces contamination continuously and deals with periodic contamination. Similar to surface waters, monitoring for contamination is necessarily intermittent, especially for small systems. Moreover, in 1982, about 24 percent of the utilities violated coliform monitoring requirements at least intermittently and 14 percent violated turbidity monitoring requirements.

A variety of disinfectants are available. Currently, the best are chlorine (as hypochlorous acid), ozone, and chlorine dioxide. All three have excellent biocidal activities against bacteria and viruses. For inactivation of protozoan cysts, ozone is excellent, chlorine has only moderate biocidal activity, and no published data are yet available for chlorine dioxide. Chlorine and chlorine dioxide residuals can persist in the distribution system, ozone residuals cannot. Besides these three disinfectants, others are being used or have been suggested for use. These include chloramines, iodine, bromine, and ultraviolet light. A treatment regulation will recommend the types of disinfectants appropriate for use, the range of acceptable disinfectant concentrations, minimum contact times, and possibly the minimum and maximum residual concentrations in the distribution system. Variances would be considered in those circumstances where a system is able to demonstrate to the satisfaction of the State that the source water is of sufficiently good quality to obviate the need for disinfection. Like the surface water regulation, criteria to assist in making variance determinations would be provided if a regulation is proposed.

Public comment is requested on the following:

- Should a treatment technique requirement be established such that systems using ground water would be required to provide disinfection? Upon what basis?
- What specific disinfection technology should be included in the regulation?
- Should these treatment requirements apply to non-community drinking water systems?
- What criteria should be specified for the issuance of variances?

VII. Inorganic RMCLs

The Interim Regulations contain MCLs for the following ten inorganic chemicals:

Contaminant	MCL, mg/l
Arsenic	0.05
Barium	1
Cadmium	0.010
Chromium	0.05
Fluoride	1.4 to 2.4, depending on climate.
Lead	0.05
Mercury	0.002
Nitrate (as N)	10
Selenium	0.01
Silver	0.05

Monitoring and reporting requirements were also included in the Interim Regulations for sodium and corrosion.

The ANPRM (48 FR 45502) listed 23 IOCs under consideration for Primary Drinking Water Regulations. RMCLs are proposed for 11 IOCs (one of which was not listed in the ANPRM—nitrite), one IOC (fluoride) will be included in a separate proposal, and 6 IOCs (cyanide, molybdenum, nickel, silver, sodium, and sulfate) have been determined inappropriate for regulation based upon limited health effects data and/or occurrence in drinking water. Five IOCs (antimony, beryllium, thallium, vanadium and aluminum) will be addressed at a later date and one IOC (zinc) has been determined inappropriate for regulation based upon EPA and the National Academy of Sciences (1977 and 1980) reviews.

For the 11 inorganic chemicals for which RMCLs are proposed, the Administrator has determined that human exposure to these IOCs in drinking water may have an adverse effect upon the health of persons.

Table 8 presents the proposed RMCLs for the 11 IOCs. Table 9 summarizes the short-term assessments for those chemicals for which RMCLs are proposed and Table 10 summarizes the short-term assessments and provisional

AADIs for those chemicals for which RMCLs are not proposed.

Presented in this section are (1) a discussion of analytical methods available for measurement of IOCs and (2) separate discussions for each IOC on (a) the occurrence in drinking water and the relative contributions from drinking water, air and food, and (b) the potential health effects of exposure. In this notice, EPA is presenting a summary of those analytical methods that appear to be available. In the MCL proposal, EPA will propose methods that have been determined to be economically and technologically feasible.

In the discussion of health effects, information on 1-day exposure, 10-day exposure and chronic toxicity effects is included. In addition, a summary of health-related guidelines prepared by other groups and organizations is presented for each IOC. Levels that have been calculated by the WHO, the NAS and EPA's Office of Water Regulations and Standards (Water Quality Criteria) have been included. In several instances, these values differ from the proposed AADIs. This is due to several different factors, including the use of different uncertainty factors, different interpretations of data and varying assumptions. In some cases, new data may have become available resulting in the derivation of an AADI which differs from the earlier calculated values. This section closes with a description of the toxicological basis for the proposed RMCL. This includes calculations of Adjusted Acceptable Daily Intakes (AADI's) for threshold toxicants and, in addition, a risk assessment for substances that are being proposed for regulation as potential human carcinogens. Issues are identified for which public comments are requested on each of the IOCs. The information presented here is summarized from the supporting documents on analytical methods, occurrence, and health effects referenced in Section X.

A. Availability of Analytical Methods

Analytical methods are available for the determination of all the IOCs for which RMCLs are proposed in this notice with the exception of asbestos. Preliminary assessments have been conducted of existing methodologies to determine their suitability in terms of performance, cost, complexity, and other factors such as the availability of trained personnel to conduct the analyses. Specific analytical methods for each contaminant will be proposed as part of the MCL proposal along with specific criteria for the determination of acceptable performance for those laboratories conducting compliance analyses.

TABLE 8.—PROPOSED RMCLS FOR IOCS

IOC	Provisional AADI [4] (mg/l)	Proposed RMCL [5] (mg/l)
Arsenic	0.10	0.050 [1]
Asbestos (medium and long fibers).		7.1 million fibers/liter [6]
Barium	1.8	1.5
Cadmium	0.018	0.005
Chromium	0.17	0.12
Copper	1.3	1.3 [2]
Lead		0.020
Mercury	0.005	0.003
Nitrate	10.0	10.0 [3]
Nitrate	1.0	1.0 [3]
Selenium	0.106	0.045

[1] Based on NAS recommendation and data which suggest that arsenic may be an essential nutrient.
[2] Based on acute toxicity.
[3] Based on acute toxicity for infants up to 3 to 6 months of age.
[4] The AADIs were determined from studies of less than lifetime duration (approximately 2 years for an animal study).
[5] Based upon Provisional AADI with drinking water contribution factored in.
[6] Based upon classification in Category II as a possible carcinogen using a 10^{-5} cancer in risk level. Limited to fibers longer than 10 um.

TABLE 9.—SHORT-TERM ASSESSMENTS FOR IOCS FOR WHICH RMCLS ARE ALSO PROPOSED

IOC	1-Day (mg/l)		10-day (mg/l)		Longer-term [1] (mg/l)	
	Child	Adult	Child	Adult	Child	Adult
Arsenic	0.05	0.05	0.05	0.05	0.05	0.05
Asbestos	NA	NA	NA	NA	NA	NA
Barium	NA	NA	NA	NA	NA	NA
Cadmium	0.043	0.150	0.008	0.029	NA	NA
Chromium (VI)	NA	NA	1.4	5.0	0.24	0.84
Copper	1.3	1.3	NA	NA	NA	NA
Lead	NA	NA	NA	NA	NA	NA
Mercury	NA	NA	NA	NA	NA	NA
Nitrate	NA	NA	[2] 10	111	NA	NA
Nitrite	NA	NA	[2] 1	11	NA	NA
Selenium	NA	NA	0.045	0.144	NA	NA

NA = Not available. Adequate dose-response data are not available. Assessment derived for the next longer duration of exposure is considered to be protective in these cases.
[1] The longer-term numbers are not discussed in the individual *FR Notice* sections but the rationale for the numbers are discussed in the Health Advisory documents.
[2] Based on a 4 kg infant. For rationale see the Health Advisory for nitrate/nitrites.

TABLE 10.—SHORT-TERM ASSESSMENTS AND PROVISIONAL AADIS FOR IOCS FOR WHICH RMCLS ARE NOT PROPOSED

IOC	1-day (mg/l)		10-day (mg/l)		Provisional AADI (mg/l)	Guidance level (mg/l)
	Child	Adult	Child	Adult		
Aluminum	NA	NA	NA	NA	NA	[4] 0.05
Cyanide	NA	NA	0.22	0.75	0.75	0.75
Molybdenum	2.7	9.5	0.27	0.95	0.10	NA
Nickel	NA	NA	1.0	3.5	0.350	[5] 0.150
Silver	NA	NA	NA	NA	0.090	0.090
Sodium						[1] 20
Sulfate						[3] 400
						[3] 250

NA = Not Available. Adequate dose-response data are not available. Assessment derived for the next longer exposure duration is considered to be protective in these cases.
[1] For high risk individuals on sodium restricted diets. EPA will also prepare secondary standards based upon aesthetic quality.
[2] For protection of the infant as a sensitive subpopulation.
[3] Based on taste and odor.
[4] Based upon avoidance of post precipitation in the distribution system. Aluminum would be a candidate for a secondary standard.
[5] Provisional AADI with data on human exposure factored in.

Table 11 provides a listing of several analytical methodologies for the IOCs and estimated detection limits.

Two method validation studies have been conducted for the furnace atomic absorption (AA) and the inductively coupled plasma (ICP) atomic emission spectrometry techniques. Analytes include all the metals listed in Table 11

analyzable by these techniques. Other performance related data are being gathered from ongoing performance evaluation studies conducted by EPA's Environmental Monitoring and Support Laboratory in Cincinnati, Ohio (EMSL-CIN) for all IOCs included in this RMCL proposal, with the exception of asbestos. These data will be the basis for the analytical methods and performance criteria which will be proposed when the MCLs are proposed.

TABLE 11.—ANALYTICAL METHODS FOR IOC'S

IOC and Methodology	Approximate detection limits (µg/l)	References		
		EPA	16th edition Std. methods	ASTM
Aluminum:				
AA Flame	100.0	202.1	303 C or D	D 857-79 D or E.
AA Furnace	3.0	202.2	304	
ICP	45.0	200.7		
Arsenic:				
AA; gaseous hydride	2.0	206.3	303 E	D 2972-78 B.
AA Furnace	1.0	206.2	304	
ICP	3.0	200.7		
Asbestos: Transmission Electron Microscopy				
Barium:				
AA Flame	100.0	208.1	303 C	
AA Furnace	2.0	208.2	304	
ICP	0.4	200.7		
Cadmium:				
AA Flame	5.0	213.1	303 A or B	D 3557-78 A or B.
AA Furnace	0.1	213.2	304	
ICP	1.0	200.7		
Chromium:				
AA Flame	50.0	218.1	303 A or B	D 1687-77 D.
AA Furnace	1.0	218.2	304	
ICP	0.6	200.7		
Copper:				
AA Flame	20.0	220.1	303 A or B	D 1688-77 D, E.
AA Furnace	1.0	220.2	304	
ICP	6.0	200.7		
Cyanide:				
Distillation; Colorimetric	20.0	335.2	412 B or D	
Automated Electrode	50.0		412 E	
Lead:				
AA Flame	100.0	239.1	303 A or B	D 3559-78 A or B.
AA Furnace	1.0	239.2	304	
ICP	5.0	200.7		
Mercury:				
Manual Cold Vapor Technique	0.2	245.1	303 F	D 3223-79.
Automated Cold Vapor Technique	0.2	245.2		
Molybdenum:				
AA Flame	100.0	246.1	303 C	
AA Furnace	1.0	246.2	304	
ICP	8.0	200.7		
Nickel:				
AA Flame	40.0	249.1	303 A or B	D 1886-77 C or D.
AA Furnace	1.0	249.2	304	
ICP	15.0	200.7		
Nitrate:				
Colorimetric Brucine	100.0	352.1		
Spectrometric; Cadmium Reduction	10.0	353.3	418 C	D 3867-79 B.
Automated Hydrazine Reduction	10.0	353.1		
Automated Cadmium Reduction	50.0	353.2	418 F	D 3867-79 A.
Nitrite: Spectrophotometric	10.0	354.1	419	
Selenium:				
AA; gaseous hydride	2.0	270.3	303 E	D 3859-79.
AA Furnace	2.0	270.2	304	
ICP	1.0	200.7		
Silver:				
AA Flame	10.0	272.1	303 A	D 3866-82 A or B.
AA Furnace	0.2	272.2	304	D 3866-82 C.
ICP	75.0	200.7		
Sulfate:				
Turbidimetric	1,000.0	375.4	426 C	D516-82B.
Colorimetric; Automated	3,000.0	375.2		
Sodium:				
AA Flame	2.0	273.1		
AA Furnace	0.2	273.2		
Flame Photometry	10.0		325 B	D 1428-64 A.

B. Proposed RMCLs

1. Arsenic

Arsenic occurs naturally and is commonly found as arsenic sulphide or as an impurity in various minerals and as arsenate or arsenite. In particular, arsenic is found in ores of copper, lead, zinc, iron, managanese, uranium, and gold. Most of the arsenic produced is a by-product of the smelting of copper, lead, and zinc ores. Areas with elevated levels of arsenic in geologic materials are found throughout the United States, mostly concentrated in the eastern States. Some coals, particularly from eastern States, have a high arsenic content.

Arsenic has been found in both ground water and surface waters; generally ground waters tend to contain higher arsenic levels than surface waters. Arsenic in water can result from both natural processes and industrial activities, including smelting operations, use of arsenical pesticides, and industrial waste disposal.

Analytical Methods. Analytical methods available for analyzing elemental arsenic in drinking water

include the atomic absorption, gaseous hydride, furnace atomic absorption and inductively coupled plasma atomic emission spectrometry techniques.

Human Exposure. Arsenic enters the atmosphere as a result of the smelting of non-ferrous ores, mostly copper; glass production plants, coal burning facilities, and arsenical compound production plants may also emit arsenic to the air. Data collected by EPA and others show the level of arsenic in air ranges from 0.0005–1.5 ug/m^3; the median value is typically less than 0.01 ug/m^3. Respiratory intake of arsenic on a daily basis is approximately 0.12 ug of which 0.03 ug would be absorbed, assuming 30 percent absorption and based on a 1981 national average air value of 0.006 ug/m^3 of air and a daily ventilation rate of 20 m^3.

Arsenic, primarily in an organic form is a normal constituent of food. Seafoods tend to have particularly high arsenic levels. Meat, fish, poultry, grain, and cereals also contain arsenic. The FDA estimated in its 1979 market basket survey that adults consume 61.5 ug/day of arsenic in the diet.

Sixty-three community water supplies in the United States have been reported to exceed 50 ug/l of arsenic. Limited data from two federal surveys indicate that water supplies using ground water had arsenic present above the detection limit more frequently and at higher concentrations than supplies using surface water. Of 330 ground water supplies sampled in the two surveys, 55 (16.7%) had levels above 5 ug/l; of the 115 surface water supplies, only 2 (1.7%) had levels above 5 ug/l.

Health Effects. Arsenic compounds have been shown to produce acute and chronic toxic effects which include systemic irreversible damage. The trivalent (+3) compounds are the most toxic and tend to accumulate in the body. Chronic animal studies have shown body weight changes, decreased blood hemoglobin, hepatic damage and kidney damage.

There is evidence that arsenic is an essential element in certain animal species and potentially in humans. Arsenic at low concentrations in the diet enhances some parameters of growth and development in animals and it has been suggested that arsenic may be an essential element for humans (NAS, 1980. *Drinking Water and Health,* Vol. III).

EPA's Risk Assessment Forum is currently evaluating the nutritional requirements for arsenic. A comprehensive literature search examining the available data on the possible essentiality of arsenic is being carried out.

The NAS (*Drinking Water and Health,* 1983. Vol. V) reevaluted the toxicity of arsenic and stated that,

> Research should also be designed to evaluate the possible essentiality of arsenic for humans—a requirement that has been demonstrated in four mammalian species. In the absence of new data, the conclusion reached in the third volume of *Drinking Water and Health* remains valid, i.e. 'If 0.05 mg/kg of dietary [total] arsenic is also a nutritionally desirable level for people, then the adequate human diet should provide a daily intake of approximately 25 to 50 ug. The current American diet does not meet this presumed requirement' (National Research Council, 1980). The unresolved status of this issue is further reason for maintaining the current MCL for arsenic.

In addition, the NAS Safe Drinking Water Committee stated that "it is therefore the opinion of this committee that 0.05 mg/l provides a sufficient margin of safety. . . ." Based on the specific recommendations of the NAS, EPA proposes that all Health Advisories for arsenic be 0.05 mg/l.

A provisional AADI was calculated based upon an animal study (Heywood, R. and R.J. Sortwell, 1979. Arsenic Intoxication in the Rhesus Monkey. Toxicol. Lett. 3:137–144) in which adolescent and infant Rhesus monkeys were exposed to arsenic for one year. A NOAEL of 3.74 mg/kg/day arsenate (2.8 mg As/kg/day) was selected, with an uncertainty factor of 1000 and consumption of 2 liters of water per day factored in. A provisional AADI of 0.10 mg/l was determined from this study.

Arsenic has been shown to be mutagenic in several test systems and to induce chromosomal aberrations in *in vivo* and *in vitro* systems. Carcinogenicity studies with laboratory animals have reported conflicting results. Several studies have reported an increased incidence of bronchiogenic carcinomas in rats exposed to an arsenic-containing pesticide through intratracheal exposure. In humans, tumors of the skin, lungs, genital organs and visual organs have been associated with arsenic exposure.

The IARC evaluated arsenic and stated that there is evidence that arsenite and arsenate cross the placenta in mammals and that sodium arsenate and arsenite have embryolethal effects and teratogenic potential in several mammalian species. The IARC classified arsenic compounds in Group 1; inadequate evidence for carcinogenicity in animals and sufficient evidence that inorganic arsenic compounds are skin and lung carcinogens in humans. They also stated that the data suggesting an increased risk for cancer at other sites are inadequate for evaluation. Arsenic has been classified in EPA's Group A, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon evidence of human carcinogenicity through inhalation and ingestion exposure.

EPA's Office of Research and Development commissioned a report (Andelman, et al. 1983. Feasibility Study to Resolve Questions of the Relationship of Arsenic in Drinking Water to Skin Cancer. Submitted to Office of Research and Development, U.S. EPA) to examine the available epidemiologic studies which looked at the relationship between arsenic exposure and skin cancer in the United States. The conclusion of the report was that the studies performed to date lacked sufficient power to definitively determine if arsenic causes skin cancer. However, the report stated that the precursors of skin cancer (increases in skin pigmentation and callous formation) were not seen in these studies and these precursor effects would normally be seen in cases of arsenic-induced skin cancer.

Based upon the specific recommendations of the NAS, EPA proposes that the RMCL for arsenic remain at the current MCL of 0.050 mg/l. This level is below the concentration at which toxicity is demonstrated and is in the range which may be essential for humans (*Drinking Water and Health,* 1983. Vol. V).

EPA considered using 0.10 mg/l as the proposed RMCL, based upon the provisional AADI. It was determined that the RMCL should not be based upon this data, because an insufficient number of animals (4 per dose group) were studied.

Zero or some other value for the RMCL based upon the carcinogenic potential for arsenic was also considered. However, studies of drinking water related arsenic exposure have not detected increased risks via drinking water in the USA. Because evidence suggests that arsenic may be an essential element, setting the RMCL at zero would not take into account the possible beneficial effects from arsenic exposure.

The WHO guideline for arsenic is 0.050 mg/l which is the same level that EPA is proposing for the RMCL. This value was based upon human data which suggests that a concentration of 50 μg/l of arsenic per liter is not associated with any adverse health effects. In addition, the WHO stated that at an arsenic concentration of 50 μg/l, the contribution made by water to the daily intake will normally be about

one-half to two-thirds and for very low dietary intakes of arsenic, the proportion provided by water may be somewhat higher. The WHO concluded that arsenic in drinking water will normally be the main source of inorganic arsenic.

EPA's CAG has calculated excess cancer risk values for arsenic (U.S. EPA. 1980. Ambient Water Quality Criteria for Arsenic. EPA 440/5–80–02). CAG calculated that concentrations of 22 ng/l, 2.2 ng/l, and 0.22 ng/l would result in an incremental increase of cancer risk over the lifetime at 10^{-5}, 10^{-6} and 10^{-7}, respectively. These values were calculated based upon a study of increased incidence of skin cancer in humans in Taiwan (Tseng, et al. 1968. Prevalence of Skin Cancer in an Endemic Area of Chronic Arsenicism in Taiwan. Jour. Natl. Caner Inst. 40:453).

EPA is proposing to regulate arsenic because of the potential adverse health effects and its widespread occurrence. Based upon the NAS recommendations, an RMCL of 0.050 mg/l is proposed. Comments are requested on all of the issues outlined below, and comments are specifically requested on the appropriate level for the RMCL.

Questions for Comment:

1. How should the proposed nutritional essentiality of arsenic be considered in determining the RMCL?

2. Is 0.050 mg/l an appropriate level for the RMCL, or should the provisional AADI (0.10 mg/l) or another value be used?

3. Should arsenic's carcinogenic potential alone be used in setting the RMCL?

2. Asbestos

Asbestos is a commercial term applied to a group of highly fibrous, hydrated silicate minerals. These minerals separate into long, thin, strong fibers that are heat resistant and chemically inert, and which possess sufficient flexibility to be woven. Asbestos minerals belong to the serpentine or amphibole groups. The amphiboles are further divided into the orthorphobic crystal system and the monoclinic crystal system. Of the commercially mined and processed asbestos minerals, chrysotile (serpentine group) accounts for 95 percent of production.

There are literally thousands of recorded uses of asbestos minerals in the U.S. The major uses, however, are in production of cement products, floor tiles, paper products, paint, and caulking; in transportation-related applications; and in the production of textiles and plastics.

Analytical Methods. The analytical determination of asbestos in drinking water presents a unique problem. Asbestos is a generic designation for a group of minerals of various compositions. Therefore, the accurate determination of asbestos requires the identification, characterization and measurement by counting the number of particles possessing the required fibrous shape, crystalline structure and elemental composition. The best existing technique for this purpose consists of separation of fibers and quantitation by transmission electron microscopy and identification by X-ray diffraction. The accuracy of this method is highly sensitive to the quality of the water sample and to the presence of interfering substances. A major drawback is the initial capital outlay of approximately $200,000 for equipment, the analytical cost of approximately $500 per sample and requirements for specialized facilities and personnel. Thus, monitoring is not considered to be technologically and economically feasible for all types and lengths of asbestos fibers for compliance purposes in public water systems.

Three different approaches have been investigated to develop a simpler, faster and cheaper measurement method for asbestos. These approaches depend upon light scattering properties of particulates (turbidimetric and magnetic alignment-light scattering methods), or surface properties of chrysotile asbestos which is selectively extracted into iso-octane in the presence of a surfactant (two phase liquid separation method). The most promising method is the one based on magnetic alignment-light scattering.

Optical microscopy may be used to screen water samples to measure fibers above a certain length. Fibers with a minimum length of 5 micrometers and about 0.5 micrometers in width can be measured using this method, with the analytical costs estimated at $50–$100 per sample and an initial outlay of approximately $1,500 for an optical microscope. This technique characterizes fiber shapes only and does not discriminate between asbestos and non-asbestos types. However, the technique could be useful for screening to determine which samples should be analyzed more intensively using transmission electron microscopy or for surveillance after the fibers in a water supply had been characterized by x-ray diffraction or transmission electron microscopy.

Human Exposure. The NAS (1984) have reported an air concentration of asbestos of 0.0004 ug/cm³ as typical to an urban dweller, combining indoor and outdoor exposure. The daily exposure through inhalation of ambient air would be approximately 3000 fibers/day at a ventilation rate of 20 m³ for the adult male.

No information was available from the FDA on the occurrence of asbestos in food. Some wines have been shown to contain as much as 64 million fibers of asbestos per liter (MFL).

Levels of asbestos fibers in drinking water have been summarized by EPA (1980) for 406 cities in 47 States, Puerto Rico, and the District of Columbia. The distribution of reported asbestos concentrations is presented below:

Highest asbestos concentration, 10^6 fibers/1	Number of cities	Percentage
Below detection limits	117	29
<1	216	53
1 to 10	33	8
>10	40	10

In 1981, EPA summarized the results of a nationwide sampling for asbestos in drinking water from 100 systems. Samples were taken from a representative point in the distribution system of each utility. Levels above detection of 0.08 MFL were found in twelve of the 100 systems. Levels ranged from 0.385 to 1,071 MFL. These data and other data from various State studies indicate that asbestos occurs in various drinking water supplies across the country as a result of asbestos in the raw water supply or as a result of corrosion of asbestos-cement pipe in the distribution system.

Human exposure to asbestos in drinking water occurs primarily via ingestion but exposure via inhalation can occur as a result of the use of humidifiers and possibly showers. However, data are limited on these sources of exposure.

Health Effects. A wide range of effects have been observed following exposure via inhalation to asbestos particles. This is in contrast to exposure via ingestion where the only effects reported in animals at very high levels were changes in the mucosal lining cells of the ileum and changes in the colon, rectum and small intestine.

Inhalation studies have shown that various forms of asbestos have produced lung tumors and mesothelioma in laboratory animals. The majority of asbestos ingestion studies have failed to produce carcinogenic effects in animals. The National Toxicology Program (NTP) investigated the carcinogenic potential of the ingestion of amosite and tremolite asbestos in rats. No toxicity or increase in neoplasia was observed in tremolite-exposed rats, while significant increases

in C-cell carcinomas of the thyroid and monocytic leukemia in male rats were observed in the amosite-exposed group.

The NTP concluded that: (1) The biological significance of the C-cell carcinoma in relation to amosite exposure is discounted because of a lack of significance when C-cell adenomas and carcinomas were combined and the positive effect was not observed in the amosite plus preweaning gavage group, and (2) the biological significance of an increased incidence of mononuclear cell leukemia is questionable because of a lack of statistical significance in the amosite group when evaluated using life table analysis.

Recently, NTP has reported the results on the toxicology and carcinogenesis of chrysotile asbestos in F344/N rats (NTP. 1984. Toxicology and Carcinogenesis Studies of Chrysotile Asbestos in F344/N Rats. Draft Report). In this report, the NTP has concluded that "there was some evidence of carcinogenicity" in male rats only that were exposed to one percent intermediate range (IR) chrysotile asbestos in the diet for the lifetime of the animals. This preliminary conclusion was based on the following observations: (1) A significant increase in benign epithelial neoplasms (adenomatous polyps) in the large intestine of IR chrysotile asbestos male rats (9/250; 3.6%) when compared with the incidence of epithelial neoplasms (benign and malignant combined) of the large intestine in the pooled male control groups of all the NTP oral asbestos lifetime studies (3/524; 0.6%), (2) the incidence of similar lesions in the small intestine or glandular stomach of five additional IR chrysotile male rats, and (3) the rare occurrence of epithelial neoplasm lesions in F344/N rats (1/1,727 for male rats and 0/1,777 for female) is standard.

There have been a number of epidemiological studies which showed gastrointestinal cancer to be associated with occupational exposure to asbestos. The consistency of an increased cancer risk at extrathoracic sites and its magnitude, either in absolute or relative terms, is less for cancer at other sites than for lung cancer. Nevertheless, many studies document significant cancer risks at various gastrointestinal sites. Even though these studies document definite evidence of association of observed gastrointestinal cancer risk and elevated lung cancer in workers, the question of whether the observed increased risk of gastrointestinal cancer is due to the ingestion of inhaled asbestos in the occupationally exposed workers is not resolved at this time. The Chronic Hazard Advisory Panel on Asbestos (U.S. CPSC Draft Report, 1983) has stated the following: "Lung cancer and mesothelioma constitute the majority of asbestos produced cancers. The association of these malignancies with asbestos exposure is firmly established. Some other forms of cancer, particularly digestive tract, oral pharyngeal, laryngeal, and kidney have, in some large studies, been found to be increased; there are disagreements among Panel members as to the strength of the evidence associating this group of cancers with asbestos exposure." A report prepared for the Health and Safety Commission of the United Kingdom examined the available evidence on the health effects of inhaled asbestos and concluded, "In particular, there are no grounds for believing that gastrointestinal cancers in general are peculiarly likely to be caused by asbestos exposure. The increase in relative risk for gastrointestinal sites is similar to that for other sites, and their selection for special attention appears to have been dictated largely by the findings in one study and the fact that they are common, so that a given observed relative risk may be statistically significant for these sites but not for others."

The IARC has classified asbestos in Group 1; sufficient evidence for carcinogenicity in animals and humans. This classification is based upon inhalation data. Asbestos has been classified in EPA's Group A, according to EPA's Proposed Guidelines for Carcinogen Assessment, based upon evidence of carcinogenicity in humans through inhalation exposure.

Several epidemiological studies have been carried out investigating potential associations between asbestos fibers in drinking water and gastrointestinal cancer. Marsh (Environ. Health Persp. 1983. 53:49–56) reviewed and evaluated thirteen epidemiological studies of ingested asbestos in five areas of the United States and Canada for the risk associated with ingestion of water containing asbestos. He concluded that even though one or more studies found association between asbestos in water supplies and cancer mortality (or incidence) due to neoplasms of various organs, no individual study or aggregation of studies exists that would establish risk levels from ingested asbestos.

EPA's CAG (1980) and the NAS (1983) have extrapolated the results of cohort studies of populations occupationally exposed via inhalation in order to estimate the potential risk associated with the ingestion of asbestos in drinking water. The CAG (U.S. EPA. 1980. Ambient Water Quality Criteria for Asbestos. EPA 440/5–80–022) and the NAS (*Drinking Water and Health*, 1983. Vol. V) considered much the same data of occupationally exposed workers with GI tract cancers, but use a slightly different method of calculating the excess cancer risk values. The estimated levels which would result in increased lifetime cancer risks of 10^{-5}, 10^{-6}, and 10^{-7} calculated by CAG (1980) are 300,000 fibers/1, 30,000 fibers/1 and 3,000 fibers/1, respectively. Corresponding numbers for males calculated by the NAS (1983) are 110,000 fibers/1, 11,000 fibers/1 and 1,100 fibers/1. The more restrictive levels calculated by the NAS compared to CAG are primarily due to the application of two different assumptions:

(1) The NAS assumed that 30 percent of the inhaled fibers were subsequently swallowed, where the CAG assumed that 100 percent would eventually be cleared and ingested.

(2) The NAS assumed a conversion factor of 50 for optical microscopy to transmission electron microscopy, where the CAG assumed a factor of 200.

The available information on the risk of developing gastrointestinal tract cancer associated with the ingestion of asbestos from drinking water is limited. Risk projections based upon ingestion studies would appear to be more appropriate than inhalation for exposures via drinking water. CAG (1984) has derived an estimate of the risk for asbestos by injestion based upon a draft NTP (1984, draft report) ingestion study of chrysotile short range (98% <10 um) and intermediate range (65$>$ 10um; with $-14\%>$ 100um) fibers in animals. The results of this study showed no evidence of carcinogenicity for the short-range fibers in either male or female rats and no evidence of carcinogenicity for the intermediate range fibers in the female rats. However, there was an increase in benign polyps of the large intestine for the male rats ingesting the intermediate range fibers (>10 um) at 1 percent of the diet. Although not statistically significant compared with the concurrent controls, the incidence of these neoplasms was highly significant when compared with the incidence of epithelial neoplasms (benign and malignant combined) of the large intestine in the pooled control groups of all the NTP oral asbestos lifetime studies. If indeed a cause/effect can be deduced from this experiment, CAG calculated, based upon the one-hit model, that 7.1×10^{7}, 7.1×10^{6} and 7.1×10^{5}

fibers/1, would result in a lifetime excess cancer risk of 10^{-5}, 10^{-6} and 10^{-7}, respectively. These levels are calculated for the intermediate range chrysotile fibers only. As such, the levels are much more restrictive than they would have been had they incorporated the study using the short range chrysotile fibers. The short range chrysotile fiber study showed no effects with 50 times the number of fibers as the intermediate range study. If the short range study had been included with the data from the intermediate range study had been included with the data from the intermediate range study, levels would have been at least 10 times higher (i.e., less restrictive). Conversely, if the shorter fiber had been eliminated from the positive intermediate fiber study, levels would have been lower by a factor of about 2.5.

While significant efforts have been expended to determine the potential human health risks of exposure to asbestos via drinking water, questions still remain. Summarizing:

- Asbestos has carcinogenic effects via inhalation exposure in humans.
- Animal studies consisting of oral exposure to asbestos were negative except in one experiment in the recently reported NTP study (draft report, 1984).
- Epidemiology studies examining asbestos in drinking water have not found consistent credible correlations between carcinogenic effects and asbestos.
- Evidence exists which shows increased risk of gastrointestinal cancer from inhalation of asbestos fibers during occupational exposure. However, questions have been raised as to whether the gastrointestinal cancer was caused by swallowing inhaled fibers or due to other mechanisms.

EPA's Science Advisory Board (SAB) examined the question of the carcinogenic potential of ingested asbestos in 1984 but without access to the latest NTP report of benign adenomateous polyps in male rats. They concluded:

> Given the positive signal seen in some epidemiologic studies, plus well-documented evidence for the association between asbestos fiber inhalation and lung cancer, it is hard for the Committee to feel comfortable in dismissing the possibility of an increased risk of gastrointestinal cancer in humans exposed to asbestos fibers from drinking water. However, the Committee consensus is that current peer-reviewed evidence for humans and animals does not support the view that asbestos ingested in water causes organ-specific cancers.

The SAB reexamined the issue in 1985, considering whether the increased incidence of benign polyps reported in the NTP study was sufficient to conclude that carcinogenicity was demonstrated under the conditions of the study. The SAB concluded that the data were equivocal and reaffirmed their 1984 conclusions as summarized above.

EPA has considered two main regulatory options for asbestos in drinking water. The first option consists of not proposing a primary regulation for asbestos, due to the inconclusive nature of the data. Animal studies (except for the recently reported NTP study) have not shown a correlation between oral exposure to asbestos and carcinogenic effects and epidemiologic studies examining asbestos in drinking water have not shown a consistent relationship between asbestos and carcinogenic effects. Thus, EPA could conclude that sufficient evidence is not available to demonstrate that asbestos in drinking water is associated with organ-specific cancers and an RMCL is not warranted. As a suboption, EPA could prepare a health advisory based upon the data from the NTP study but it would be in the form of guidance rather than enforceable standard.

The second option consists of proposing an RMCL for asbestos fibers exceeding 10 um in length. The basis for this option is that asbestos has been shown to be a human carcinogen through inhalation exposure and data exists which suggests that asbestos may be associated with an increased risk of gastrointestinal cancer through occupational exposure. The results of the NTP study showed an association in male rats between ingestion of asbestos fibers greater than 10 μm in length and gastrointestinal tumors that may be indicative of carcinogenic effects. In addition, evidence exists to support the association between asbestos fiber length and carcinogenic effects: inhalation exposure to medium and long (>10um) fibers have been shown to result in mesotheliomas in rats while nonfibrous particulates have not been shown to cause tumors. Asbestos would be considered to have equivocal evidence of carcinogenicity in drinking water (Regulatory Category II) and the RMCL would be proposed at the 10^{-6} risk levels (i.e., 7.1×10^{6} fibers/liter). Comment would then be requested on whether there is an available analytical method for asbestos. If so, an MCL for long fibers would be proposed. If it is determined that an analytical method was not available, a treatment regulation would be proposed.

EPA is proposing an RMCL for asbestos (Option #2) at the present time and is soliciting public comment on the asbestos issue. An RMCL is being proposed based upon the widespread occurrence of asbestos in public water supplies, data showing that asbestos is carcinogenic in humans through inhalation exposure, and data showing that fiber lengths greater than 10 μm may be carcinogenic through ingestion exposure. EPA will reconsider this option based upon any new data and the public comments received.

Questions for Comment:

1. Are there sufficient data upon which to regulate asbestos as a possible human carcinogen by ingestion (Category II)?
2. Is there a sufficient basis for EPA to regulate asbestos fibers exceeding 10 μm in length based upon the recent NTP bioassay in male rats?
3. Is the analytical method technologically adequate to determine the level of asbestos fibers >10 μm in drinking water?
4. The RMCL for asbestos fibers exceeding 10 μm in length is proposed based upon the 10^{-6} risk level, as calculated by CAG from animal ingestion studies which considered the association between fiber length and carcinogenicity. The RMCL could also be based upon the risk levels derived by CAG from cohort studies of populations occupationally exposed via inhalation. These risk levels derived from occupational exposure do not consider fiber size in the analysis. Which of these risk calculations are more appropriate as the basis for the RMCL?

3. Barium

Barium is a naturally occurring metal found in many types of rock. Limestones, sandstones, and soils in the eastern United States may contain 300–500 ppm barium. Certain geologic formations in California, Arkansas, Missouri, and Illinois are known to contain barium levels about 1,000 times higher than those found in other portions of the United States. Areas associated with deposits of coal, petroleum, natural gas, oil shale, black shale, and peat may also contain high levels of barium. Principal areas where high levels of barium have been found in drinking water include parts of Iowa, Illinois, Kentucky, and Georgia.

The environmental release of barium is also associated with oil and gas drilling muds, coal fired power plants, fillers for automotive paints and specialty compounds used in bricks, tiles, and jet fuels.

Analytical Methods. Analytical methods available for analyzing barium in drinking water include the flame atomic absorption, furnace atomic absorption and inductively coupled

plasma emission spectrometry techniques.

Human Exposure. Barium is present in ambient air from combustion of diesel fuel, aviation fuel, coal, as well as mining refining and manufacturing. Data collected by EPA show the mean level of barium in air ranges from 0.0015–0.95 $\mu g/m^3$. Median and mean values for individual sites have generally been shown to be below 0.4 $\mu g/m^3$, which would result in an adult male having an approximate respiratory intake of 0.03–22 μg/day. The International Commission on Radiological Protection (ICRP) (1974) estimates respiratory intake to be 0.09–26 μg/day.

Little data are available on the level of barium in the U.S. food supply. It has been reported that nuts contain high levels of barium, with 1000 ppm in pecans and up to 10,000 ppm in brazil nuts. Studies on four individuals indicated the dietary intake of barium ranged from 440–1800 μg/day. The "average" value of 900 μg/day reportedly includes intake from beverages. The ICRP reports an "average" daily dietary intake of 750 μg/day for an adult male from food and fluids, of which 80 μg/day comes from drinking water. Based on these data, the diet contributes approximately 670 μg barium to the adult human intake each day.

Compliance monitoring indicates that 43 community water supplies in the United States contain more than 1 mg/l of barium (the current interim standard). Data on 132 ground water systems assembled between 1969–1980 show that approximately 14 percent of those systems contained levels of barium greater than 250 μg/l and 1–2 percent were over 1000 μg/l; data from surface water systems indicated that 14–15 percent of 28 systems contained levels of barium greater than 250 μg/l but no levels above the 500 μg/l level were found.

Health Effects. Acute exposure to barium in animals and humans results in a variety of cardiac, gastrointestinal and neuromuscular effects. Inadequate data were available to calculate shortterm assessments for barium.

The role of waterborne barium in the etiology of experimental and human "essential" hypertension remains a matter of controversy and conjecture. A provisional AADI was calculated based upon an experimental study showing chronic exposure to barium resulting in hypertension in rats (Perry, H.M., et al. 1983. Cardiovascular Effects of Chronic Barium Ingestion. In: Hemphill, D.D., ed. Proceedings of the 17th Annual Conference on Trace Substances in Environmental Health. Vol 17. Columbia, MO, University of Missouri Press, pp. 155–164). Exposure to 100 mg/l barium in drinking water for 1 to 16 months produced hypertensinogenic and cardiotoxic effects in rats. A provisional AADI of 1.8 mg/l was calculated from a LOAEL of 100 mg/l barium (5.1 mg/kg/day) with an uncertainty factor of 100, and assuming consumption of 2 liters of water per day. An uncertainty factor of 100 was applied, instead of the traditional 1000-fold uncertainty factor used with a LOAEL, based upon the minimized exposure of the rats to trace metals (i.e., calcium) in the experiment. This lack of calcium could contribute to the hypertensinogenic effects observed.

The current MCL for barium, under the National Interim Primary Drinking Water Regulations, is 1 mg/l. This value was based upon the threshold limit value (TLV) of 0.5 mg/m^3 air, assuming that 75 percent of the barium inhaled is absorbed into the blood stream and that 90 percent is absorbed via the gastrointestinal tract.

In 1982, the NAS (*Drinking Water and Health*, 1982, Vol. IV) derived a revised chronic suggested no-adverse-response level (SNARL) for barium of 4.7 mg/l. This value was derived based upon the TLV of 0.5 mg/m^3 air and assuming a 20 percent gastrointestinal absorption rate for barium in the adult human. However, animal studies indicate that young rats absorb up to 85 percent of an administered oral dose of barium compared to 7 percent absorption in adult rats. Thus, 4.7 mg/l does not appear to be applicable to the general population which would include young children who would also have an enhanced uptake efficiency over adults.

An epidemiological study of communities in Illinois demonstrated that male and female adults living in the high-barium (7.3 mg/l drinking water) community for more than ten years did not manifest significant differences in mean systolic/diastolic blood pressures (Brenniman, G.R., et al., 1981. High Barium Levels in Public Drinking Water and its Association with Elevated Blood Pressure. Arch. Environ. Health 36:28–32). However, several factors in this study have been questioned, such as confounding variables, uncontrolled parameters and data inconsistencies.

The IARC have not evaluated barium for possible carcinogenic effects. Barium has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data from animal studies.

Barium exposure has been associated with hypertension and cardiotoxicity in animals and a provisional AADI of 1.8 mg/l has been determined. For this reason and because of the widespread occurrence of barium in drinking water, EPA is proposing to continue to regulate barium. Factoring in data on human exposure (0.7 mg/day via the diet and 0 mg/day via air), the RMCL is being proposed as 1.5 mg/l. This value is five-fold lower than the barium level (7.3 mg/l) which Brenniman, et al. (1981) found to produce no effects on blood pressure in humans. It is also lower than the chronic SNARL of 4.7 mg/l derived by NAS (1982). Thus, this RCML of 1.5 mg/l contains a several-fold safety factor and should be sufficiently protective against adverse effects.

Questions for Comment:

1. Is it appropriate to base the RMCL on the hypertensinogenic and cardiotoxic potential of barium in animals?

2. Should the epidemiological study by Brenniman, et al. (1981) be used for derivation of the RMCL without additional safety factors?

3. Should the chronic SNARL value for barium of 4.7 mg/l be used as the RMCL?

4. Cadmium

Cadmium is found in very low concentrations (usually >1 ppm) in most rocks, as well as in coal and petroleum and often in combination with zinc. Geologic deposits of cadmium can serve as sources to ground water and surface water, especially when in contact with soft, acidic waters.

Cadmium uses include electroplating, nickel-cadmium batteries, paint and pigments, and plastic stabilizers. It is introduced into the environment from mining and smelting operations and industrial operations, including electroplating, reprocessing cadmium scrap and incineration of cadmium-containing plastics. The remaining cadmium emissions are from fossil fuel use, fertilizer application and sewage sludge disposal. Cadmium may enter drinking water as a result of corrosion of galvanized pipe. Landfill leachates are also an important source of cadmium in the environment.

Analytical Methods. Analytical methods available for analyzing cadmium in drinking water include the flame atomic absorption, furnace atomic absorption and inductively coupled plasma atomic emission spectometry techniques.

Human Exposure. Cadmium is introduced into the atmosphere by both natural and anthropogenic means. Higher levels are found in areas where non-ferrous metal mining, smelting and refining occur. Also, cadmium levels in air are higher in urban than in rural

areas. Cigarettes contain high levels of cadmium, and thus tobacco smokers have an increased respiratory intake of cadmium. Data collected by EPA show mean levels of cadmium in air to typically range from 0.0005–0.01 $\mu g/m^3$. Using 0.01 $\mu g/m^3$ as a typical, high value and 20 m^3/day as the ventilation rate, the respiratory intake for the adult male would be up to 0.20 μg/day.

Cadmium is present in low levels in most foods. The FDA examined 461 samples of 12 raw agricultural commodities and found cadmium to be present at or above trace (0.02 ppm) quantities in at least one sample of each product. Soybeans, peanuts, beans, wheat, and lettuce were found to have a high frequency of samples with elevated levels (>0.15 ppm). Shellfish are noted for high cadmium levels, reportedly ranging from 0.7–7.8 ppm. The FDA has estimated that daily dietary cadmium intake for the adult male is 27.2 μg (excluding beverages). Grains and cereals, potatoes, meat, fish and poultry were identified as major food categories contributing to cadmium intake.

Compliance monitoring indicates that there are currently 25 public water supplies with reported levels of cadmium above 10 $\mu g/l$, the current standard. Data on 707 ground water supplies obtained in federal surveys conducted between 1969–1980 show that about 27 percent have levels above 2 $\mu g/l$; then mean of the positives was about 3 $\mu g/l$. In the same federal survey, 19.7 percent of 117 surface water supplies had levels above 2.0 $\mu g/l$; the mean of the positives was 3.2 $\mu g/l$. None were found to exceed 10 $\mu g/l$.

Health Effects. Acute and chronic exposure to cadmium in animals and humans results in renal dysfunction, hypertension, anemia and altered liver microsomal activity. The kidney is considered to be the critical target organ in humans chronically exposed to cadmium by ingestion. The early clinical signs of renal injury include proteinuria, glucosuria and aminoaciduria.

A human study (Lauwerys, 1979. Cadmium in Man. In: Webb, ed. The Chemistry, Biochemistry and Biology of Cadmium. Elsevier/North Holland Biomedical Press, pp. 433–453) was selected for the derivation of short-term assessments for children and adults. From a NOAEL of 0.043 mg/kg/day based on the emetic effects following acute exposure in adult humans, with an uncertainty factor of 10, and assuming consumption of 1 liter (10 kg child) or 2 liters (70 kg adult) of water per day, 1-day assessments for a 10 kg child and 70 kg adult of 43 $\mu g/l$ and 150 $\mu g/l$ were determined, respectively

An animal study (Kotsonis and Klaasen, 1979. The Relationship of Metallothionein to then Toxicity of Cadmium after prolonged Oral Administration to Rats. Toxicol. Appl. Pharm. 46:39–54) was used for the derivation of 10-day assessments for children and adults. From a NOAEL of 0.08 mg/kg/day based on proteinuria following up to 24 weeks of cadium feeding in rats, with an uncertainty factor of 1,000 (an additional uncertainty factor of 10 was used due to the number of animals (6 rats) per dose group), and assuming consumption of 1 liter (10 kg/child) or 2 liters (70 kg/adult) of water per day, 10-day assessments for a 10 kg/child and a 70 kg/adult of 8 $\mu g/l$ and 29 $\mu g/l$, respectively were calculated. Those values would be very conservative because of the extended length of the test (24 weeks). These values would be considered protective of the child and adult for a one-day exposure.

A provisional AADI was calculated using renal dysfunction as an endpoint. The critical (threshold) concentration of cadmium in the renal cortex associated with renal dysfunction has been calculated to range from 50 $\mu g/g$ to 300 $\mu g/g$. A value of 200 $\mu g/g$ (Friberg, L., et al. 1974. Cadmium in the Environment, 2nd ed. Boca Raton, Florida: CRC Press Inc.; Kjellstrom, et al. 1984. Conceptual Problems in Establishing the Critical Concentration of Cadmium in Human Kidney Cortex. Env. Res. 33:284–295) has been selected as the basis of the NOAEL in the calculation of the provisional AADI. This value is probably the most widely accepted estimate of the critical concentration for renal dysfunction. Several models have been proposed to estimate the daily intake of cadmium required to reach the critical concentration in the renal cortex. Using a conservative model (Friberg, L., et al., 1974) which assumes 4.5 percent absorption of the daily oral dose and 0.01 percent excretion of the total body burden per day, a daily intake of 0.352 mg/day cadmium will be used as the LOAEL for renal effects in humans. A provisional AADI of 0.018 mg/l has been calculated using an uncertainty factor of 10 and consumption of 2 liters of water per day.

Cadmium and cadmium compounds have been shown to induce sarcomas at injection sites in animals when administered parenterally and cadmium chloride given by aerosol for 18 months can produce lung tumors in rats. The IARC have classified cadmium and certain cadmium compounds in Group 2B; limited evidence for carcinogenicity in humans, sufficient evidence for carcinogenicity in animals and inadequate evidence for activity in short-term tests. The IARC classification is based on exposure to cadmium via inhalation. However, no evidence has been found linking ingestion of cadmium with carcinogenicity in animals or humans. Cadmium has been classified in EPA's Group B1, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon evidence of carcinogenicity in humans through inhalation exposure. However, since cadmium has not been shown to be carcinogenic through ingestion exposure, the compound will be regulated based upon chronic toxicity data.

The NAS (*Drinking Water and Health*, 1982. Vol. IV) estimated a SNARL for cadmium of 0.005 mg/l based upon the same study which was used to calculate the 10-day assessment values (Kotsonis and Klaassen, 1978. The Relationship of Metallothionein to the Toxicity of Cadmium after Prolonged Oral Administration to Rats. Toxicol. Appl. Pharmacol. 46:39–54).

The current MCL for cadmium, under the National Interim Primary Drinking Water Regulations, is 0.010 mg/l. This level was based upon a cadmium level of 200 ppm in the renal cortex association with proteinuria, with 5 percent gastrointestinal absorption, rapid excretion of 10 percent of the absorbed dose and 0.05 percent daily excretion of the total body burden. It was estimated that it would take about 500–600 μg/day to cause proteinuria and with assumed diet of 75 μg/day, a drinking water level of 0.010 mg/l would provide a four-fold safety factor. The provisional AADI was also determined based upon renal dysfunction as an endpoint, but newer data were used to determine the critical concentration in the renal cortex and the daily intake of cadmium required to reach this critical concentration.

The WHO guideline for drinking water is 0.005 mg/l. This value was derived based upon the provisional, tolerable weekly intake of 0.4–0.5 person, established in 1972 by the Joint FAO/WHO Expert Committee on Food Additives. The WHO determined that a guideline value of 0.005 mg/l was suitable based upon the fact that at this concentration about one-quarter of the total cadmium absorbed might be derived from water. EPA's ambient water quality criteria for human health (U.S. EPA. 1980. Ambient Water Quality Criteria for Cadmium. EPA 440/5–80–025) is 0.010 mg/l considering ingestion of water and contaminated aquatic organisms. This value was based upon

an analysis which concluded that water constitutes only a relatively minor portion of the total cadmium intake and thus the existing drinking water standard of 0.010 mg/l was determined to provide ample protection for human health.

Because of cadmium's potential adverse health effects and widespread occurrence in raw waters, EPA is proposing to continue to regulate it in the NPDWR. The NAS and the WHO have determined guidelines of 0.005 mg/l cadmium. A provisional AADI of 0.018 mg/l has been calculated. An RMCL of 0.005 mg/l is proposed based upon the NAS and WHO guidelines which would result in a theoretical allocation to drinking water of approximately 25 percent of the ADI.

Questions for Comment:

1. Is it appropriate to use a value of 200 μg/g as the critical concentration of cadmium in the human renal cortex?

2. Is the model used to estimate the daily intake of cadmium required to reach the critical concentrations in the renal cortex based upon reasonable assumptions?

3. In the drinking water criteria document on cadmium, an alternate study is cited (Perry, et al., 1977b, 1979) for the derivation of the RMCL. Comments are requested on the use of this study in the possible derivation of the RMCL.

4. Is the use of 25 percent drinking water contribution reasonable in determining the RMCL?

5. Chromium

Chromium is a naturally occurring metal that in drinking water forms compounds with valences of +3 and +6, with the trivalent state being the more common. The average chromium content of the earth's crust has been estimated to be 40 ppm, with a range of 10–200 ppm for most geologic materials. Chromium levels of 1,000–12,800 ppm have been reported for certain ultramific rocks that are high in iron and magnesium and low in silica. The only commercial chromium ore is chromite, which occurs in small deposits in Washington, Oregon, California, Montana, Wyoming, Texas, Pennsylvania, Maryland, North Carolina, and Georgia.

Although chromium is not currently mined in the U.S., wastes from old mining operations may enter surface and ground water through runoff and leaching. Chromate wastes from plating operations may also be a source of water contamination. Fossil fuel combustion, waste incineration, cement plant emissions, chrome plating and other metallurgical and chemical operations may result in releases of chromium to the atmosphere.

Analytical Methods. Analytical methods available for analyzing chromium in drinking water include the flame atomic absorption, furnace atomic absorption and inductively coupled plasma atomic absorption emission spectrometry techniques.

Human Exposure. Data from EPA for the years 1977 to 1981 show that ambient air at most stations has mean values below 0.3 $\mu g/m^3$ (24-hour averages) and medium values below 0.2 $\mu g/m^3$. Twenty-four hour average concentrations in the U.S. for total chromium generally range between 0.005 and 0.157 $\mu g/m^3$. Maximum annual average ambient (total) chromium levels within 20 kilometers of emission sources have been predicted to range from 0.01 to 13.5 $\mu g/m^3$.

Nearly all foods contain some chromium, ranging from 20 to 590 μg/kg. The largest sources are meats, mollusks, crustaceans, vegetables and unrefined sugar. Dietary intake in humans has been estimated to range from 5 to 500 μg/day, with a typical value of approximately 100 μg/day.

Compliance monitoring data indicate that 17 ground water and one surface water supply have provided drinking water with levels greater than 50 μg/l. Twelve of the ground water supplies are small systems serving fewer than 500 people; only 3 serve more than 10,000 people and none serve more than 75,000 people. However, the one surface water supply serves more than 100,000 people.

In three national surveys conducted between 1969 and 1980, chromium was found to be present at levels above 5 μg/l in 77 of 795 ground water supplies sampled (9.7%). The mean of the positive values was 16 μg/l, with values ranging up to 49 μg/l. In surface water supplies, chromium was found at levels above 5 μg/l in 24 of 142 systems sampled (16.9%). The mean of the positives was 10 μg/l; none of the surface water supplies had values above 25 μg/l.

Health Effects. Chromium III (Cr III) and chromium VI (Cr VI) have greatly differing toxicity characteristics. Chromium III is a nutritionally essential element; the NAS (*Drinking Water and Health*, 1980, Vol. III) have estimated an adequate and safe intake level for adults of 0.05 to 0.20 mg/day via the diet. Chromium VI is much more toxic than Cr III and has been shown to produce liver and kidney damage, internal hemorrhage, and respiratory disorders. Also, subchronic and chronic exposure to Cr VI in the form of chromic acid can cause dermatitis and ulceration of the skin.

There are no suitable data available for calculating one-day assessment values for chromium III or chromium VI. However, the ten-day assessment for chromium VI of 1.4 mg/l for the 10 kg child and 5.0 for the 70 kg adult will be protective for one-day exposures.

An animal study (Gross and Heller, 1946, Chromates in Animal Nutrition. J. Ind. Hyg. Toxicol. 28:52–56) was selected to serve as the basis for calculations of the Chromium VI 10-day assessment for the 10 kg child and 70 kg adult. From a NOAEL of 14.4 mg/kg/day based on no-effects in rats following a 60-day exposure, with an uncertainty factor of 100, and assuming consumption of 1 liter (10 kg child) or 2 liters (70 kg adult) of water per day, ten-day assessments for the child and adult of 1.4 mg/l and 5.0 mg/l were calculated.

Suitable data were not available for calculating chromium III 10-day assessments for the child and the adult.

A provisional AADI for chromium (through the oral route of exposure) was determined on the basis of the effects of Cr VI and a separate AADI was not determined for Cr III for the following reasons:

1. Cr III and Cr VI are in dynamic equilibrium, the degree of oxidation in an aqueous medium depending on factors such as pH, dissolved oxygen, or presence of reducing agents. In ambient water (as opposed to sediments) there is slow oxidation of Cr III to Cr VI. The rate of this oxidation is accelerated by the addition of an oxidizing agent (MnO_2). It has been shown that water treatment involving chlorination will effectively transform Cr III to Cr VI. The normal presence of residual oxidizing capacity in treated water throughout the water distribution system will assure maintenance of dissolved chromium in the oxidized state; therefore, if chromium is present, drinking water at the point of consumption (i.e., the tap) is likely to contain substantial amounts of Cr VI.

2. Cr VI is more toxic than Cr III, since only the hexavalent species readily crosses cell membranes. The nonmutagenicity of Cr III, as contrasted with the mutagenicity of Cr VI, can be directly attributed to this fact, even though Cr III reacts with DNA in the cells. An AADI based on Cr VI, therefore, will be conservative with respect to any Cr III which might be present in water.

3. Even though orally ingested Cr VI is reduced in part to Cr III during passage through the stomach, reduction is incomplete, and there is greater absorption and greater tissue

accumulation of chromium following ingestion of Cr VI than Cr III.

A study in which rats were supplied drinking water containing up to 25 mg/l Cr VI for one year was used to calculate a provisional AADI (MacKenzie, R.D., et al. 1958. Chronic toxicity studies. II. Hexavalent and Trivalent Chromium Administered in Drinking Water to Rats. AMA Arch. Ind. Health 18:232–234). This study resulted in a NOAEL of 2.41 mg/kg/day. Using this NOAEL, an uncertainty factor of 500 based upon an animal study in which the rats were exposed to Cr VI for only 40 percent of a normal span, and consumption of 2 liters of water per day, a provisional AADI of 0.17 mg/l was determined.

The IARC have classified chromium and certain chromium compounds in Group 1 (chromium VI); sufficient evidence for carcinogenicity in humans and animals. The IARC classification is based on inhaled chromium VI. Chromium has been classified in EPA's Group A, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon positive inhalation data for chromium VI in humans and animals. However, since chromium has not been shown to be carcinogenic through ingestion exposure, the compound will be regulated based upon chronic toxicity data.

The current MCL for total chromium, under the National Interim Primary Drinking Water Regulations, is 0.05 >mg/l. This value was based upon an analysis which concluded that 0.05 mg/l chromium incorporates a reasonable factor of safety to avoid any hazard to human health.

The WHO guideline for drinking water is 0.05 mg/l for chromium, as Cr VI and also total chromium. This value was based upon the 1970 European standards for drinking water. EPA's ambient water quality criteria for human health (U.S. EPA. 1980. Ambient Water Quality Criteria for Chromium. EPA 440/5–80–035) considering ingestion of water and contaminated aquatic organisms for Cr III and Cr VI are 170 mg/l and 0.050 mg/l, respectively. These values have been updated (February 1984, 49 FR 4551) and the proposed revised values are 59 and 0.050 mg/l for Cr III and Cr VI, respectively. These values are based upon dose dependent reductions in organ weights of the liver and spleen for chromium III and the observation that the standard appears, through past experience, to be satisfactorily protective against chromium VI toxicity in humans.

Chromium exposure at high levels has been shown to result in chronic toxic effects in animals and humans by ingestion. EPA is proposing to continue regulation of this contaminant because of the potential adverse health effects and its widespread occurrence. An RMCL of 0.12 mg/l is proposed for total chromium (Cr III and Cr VI) in drinking water, based upon a provisional AADI of 0.17 mg/l with data on human exposure factored in (0.10 mg/day via the diet and 0 mg/day via air).

Question for Comment:

1. Should the RMCL calculated for chromium be based on total chromium (Cr III and Cr VI), or should separate RMCLs for the two valence states be calculated? Are the available analytical methods sensitive enough to differentiate readily between the two valence states?

6. Copper

Copper is ubiquitous in the earth's crust, occurring commonly as sulfides and oxides and occasionally as metallic copper. Weathering and dissolution of these natural copper minerals results in background levels of copper in natural surface waters at concentrations generally below 20 μg/l. The principal sources in drinking water include corrosion of brass and copper pipe by acidic waters, and other sources include use of copper salts as aquatic algacides, industrial effluents, atmospheric fallout and sewage treatment plant effluents. The major industrial sources include smelting and refining industries, copper wire mills, coal burning industries and iron and steel producing industries. Copper may enter natural water either directly from these sources or by atmospheric fallout of air pollutants produced by these industries.

Analytical Methods. Analytical methods available for analyzing copper in drinking water include the flame atomic absorption, furnace atomic absorption and inductively coupled plasma atomic emission spectrometry techniques.

Human Exposure. The principal source of elevated copper levels in air is copper dust generated by copper-processing operations. Coal-burning power plants are another source of copper emissions and tobacco smoke is a possible source.

In 1966, a National Air Sampling Network survey showed that the airborne copper concentrations were 0.01 and 0.257 $\mu g/m^3$ in rural and urban communities, respectively. Even near copper smelters, where high levels (1 to 2 $\mu g/m^3$) are reached, the dose of metal that would be acquired through inhalation of ambient air would comprise only about 1 percent of the total normal daily intake.

Copper is found in certain foods including shellfish (especially oysters) and organ meats (lamb, beef, or swine liver). Nuts, dried legumes, dried vine and stone fruits and cocoa are particularly rich in copper. The copper content of these items can range from 10 μg/g to as high as 400 μg/g. Dairy products, white sugar, and honey rarely contain more than 0.5 μg copper/g. The nonleafy vegetables and most fresh fruits and refined cereals generally contain up to 2 μg/g. Cheese, milk, beef, mutton, white and brown bread and many breakfast cereals (unless they are fortified) are relatively poor sources of copper, i.e., they have less than 50 μg copper/100 kcal. The refining of cereals for human consumption results in significant losses of copper, although this loss is not so severe as it is for iron, manganese and zinc.

A daily copper intake of 2 mg is considered to be adequate for health and normal copper metabolism. The normal daily adult intake of copper from food in the U.S. is reported to range from 2.0 to 4.0 mg per day. The reported average intake of copper in young children is 1.5 mg per day; the minimum dietary requirement is 0.10 μg/kg of body weight per day.

Water can be a significant source of copper intake depending upon the geographical location, the character of the water (i.e., hardness, pH, alkalinity), the temperature of the water and the presence of copper-containing pipes.

In 1967, the U.S. Department of Interior published the results of a five-year study of 380 finished drinking water systems. Analysis of results showed levels of copper to range from 1 to 1,060 μg/l, with a mean of 43 μg/l. In 1970, the U.S. Department of Health, Education and Welfare reported the average concentration of copper in drinking water supplies to be 134 μg/l, with a maximum concentration of 8,350 μg/l. Results of a survey of 83 water supplies by EPA Region V showed copper to range from < 5.0 to 200 μg/l in finished drinking water.

Higher copper levels have been observed in tissue samples of residents of cities with soft water. This might be due to corrosion of copper pipes and fittings, thereby increasing the intake of soluble copper. Another explanation may lie in the ability of calcium or magnesium ions in hard water to suppress the intestinal absorption of copper.

Health Effects. Copper has toxic effects at high dose levels and is an essential element at lower levels. Toxic effects resulting from acute exposure to copper in laboratory animals and

humans include gastrointestinal disturbances, hemolytic anemia, renal damage, liver damage and glucose-6-phosphate dehydrogenase inhibition. Limited data are available on the chronic toxicity of copper. Efficient homeostatic mechanisms generally protect mammals from the adverse effects of dietary copper excess. In humans, individuals with Wilson's disease are at additional risk from the toxic effects of copper. Wilson's disease is an inborn error of copper metabolism in which copper accumulates in the liver, brain and kidney, resulting in hemolytic anemia, neurological abnormalities and corneal opacities. In addition, individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency are likely to be at increased risk to the toxic effects of copper.

Copper is regarded as an essential element in mammalian nutrition because it is required in many enzymatic reactions. Copper deficiency can result in decreased iron absorption and iron deficiency, and may also lead to reproductive abnormalities. The NAS (*Drinking Water and Health*, 1980. Vol. III) has recommended an adequate and safe intake level of 2–3 mg/day copper.

One-day assessments of 1.3 mg/l for the adult and the child were determined based upon a LOAEL of 5.3 mg/day based upon human clinical case studies (Chuttani, H.R., et al. 1965. Acute Copper Sulphate Poisoning. Am. J. Med. 39:849) in which 5.3 mg was the lowest oral dose at which gastro-intestinal effects were seen. An uncertainty factor of two was applied for the following reasons: (1) The effect noted was local gastrointestinal irritation and was not permanent, (2) 5.3 mg was the lowest value determined in the literature based upon a number of studies and thus is very conservative number, (3) copper is an essential element and the application of a larger uncertainty factor would bring the level below that considered necessary for human nutrition and, (4) copper absorption is controlled by a homeostatic mechanism and the compound does not tend to accumulate in the body. Ten-day values were not calculated due to inadequate data.

A provisional AADI was determined for copper based upon the compound's acute toxicity effects, since these are the effects of concern from exposure to copper. The same LOAEL and uncertainty factor used to derive the 1-day assessments were used to determine a provisional AADI, resulting in value of 1.3 mg/l.

Copper compounds have generally provided negative results in microbial mutation assays. Copper sulfate was observed to increase the frequency of recessive lethal mutations in *D. melanogaster* at high concentrations. Equivocal results have been obtained from carcinogenicity studies. Administration of copper compounds to mice by subcutaneous injection has been reported to induce tumor formation. Orally administered copper compounds were not found to increase tumor incidence in several studies. The IARC have not evaluated the carcinogenic potential of copper. Copper has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data in humans and animals.

EPA's ambient water quality criteria for copper (U.S. EPA. 1980. Ambient Water Quality Criteria for Copper. EPA 440/5–80–036) is 1 mg/l, based upon taste and odor considerations. Copper is included in the National Secondary Drinking Water Regulations (EPA, National Secondary Drinking Water Regulations, 1979) as a secondary standard of 1.0 mg/l based upon taste and odor. The WHO has not proposed a guideline for copper based upon health effects; however they have proposed a guideline value of 1 mg/l, based upon the ability of copper to stain laundry and plumbing fixtures at concentrations above 1 mg/l.

Copper exposure at high levels may result in gastrointestinal disturbances and other acute toxic effects. For this reason and because occurrence is widespread, EPA is proposing an RMCL for copper. The RMCL will be based upon acute toxicity effects and a RMCL of 1.3 mg/l is proposed. Data on human exposure were not factored in the provisional AADI because the calculations were based upon acute effects.

Questions for Comment:

1. It there sufficient health effects information upon which to base an RMCL, or should a health advisory be developed instead?

2. Is it appropriate to base the RMCL for copper upon acute, short-term effects?

7. Lead

Lead (Pb) is a relatively rare metal in the earth's crust, ranking 34th among the elements in crustal abundance with average concentrations of 15 ppm in the continental United States.

About 65 percent of the lead produced is used for the manufacture of storage batteries; approximately 10 percent is used for gasoline additives, the second largest use. The remainder is used for pigments, ammunition, solder, plumbing, cable coverings, caulking and bearings. Although lead can be released to all media, the atmosphere is the major initial recipient of lead emissions. The main source of lead in drinking water is leaching from lead piping and services and lead solders. Airborne lead from gasoline combustion may be one of the major contributors to total lead in drinking water.

Analytical Methods. Analytical methods available for analyzing lead in drinking water include flame atomic absorption, furnace atomic absorption, inductively coupled plasma atomic emission spectrometry techniques, X-ray fluorescence, colorimetric analyses and electrochemical techniques such as stripping voltometry.

Human Exposure. Human populations in the United States are exposed to lead in air, food, water and dust. In rural areas, Americans not occupationally exposed to lead are estimated to consume 40–60 μg Pb/day. This level of exposure is referred to as the baseline exposure for the American population because it is unavoidable except by drastic change in lifestyle or by regulation of lead in foods or ambient air. Forty-four percent of the baseline consumption of lead by children is estimated to result from consumption of 0.1 g of dust per day. Ninety percent of this dust lead is of atmospheric origin (U.S. EPA, 1984, Air Quality Criteria for Lead. EPA 6008–23–028B).

Leaded gasoline combustion in vehicles accounts for about 90 percent of the total anthropogenic input of lead to the atmosphere. Atmospheric lead concentrations can range from 0.000076 $\mu g/m^3$ in remote areas to 10 $\mu g/m^3$ near point sources; EPA data show the average annual values in most areas to be below 1.0 $\mu g/m^3$. The EPA has estimated respiratory intake of lead to be about 1 μg/day for the adult and 0.5 μg/day for a 2 year old child (U.S. EPA, 1985, Occurrence of Lead in Drinking Water, Food, Air; U.S. EPA, 1984 Air Quality Criteria for Lead. EPA–600/8–83–028B).

The route by which adults and older children in the baseline population of the U.S. receive the largest proportion of lead intake is through foods. Atmospheric lead may be added to food crops in the field or pasture, during the transportation to the market, during processing, and during kitchen preparation. Metallic lead, mainly from solder, may be added during processing and packaging. Other sources of lead, as yet undetermined, increase the lead content of food between the field and dinner table. American children, adult females and adult males are estimated to consume 19, 25, and 36 μg Pb/day, respectively, in milk and nonbeverage

foods, plus an additional 7, 11, and 19 μg Pb/day, respectively, in water and other beverages. The added exposure from living in an urban environment is about 28 μg/day for adults, 91 μg/day for children and 36.2 μg/day for the 6-month old infant (U.S. EPA, 1985. Occurrence of Lead in Drinking Water, Food and Air; U.S. EPA, 1984. Air Quality Criteria for Lead).

Lead enters drinking water primarily as a result of corrosion of plumbing, particularly in areas having plumbosolvent, i.e., soft, acidic (pH<6.5) waters. Data from federal monitoring surveys show that lead was quantified (at levels above 5 μg/l) in 906 out of 1,200 (75.5%) of ground water supplies sampled. The mean of the positive values was approximately 26 μg/l, with a range of 5–380 μg/1. In surface water supplies, lead was observed at levels of about 5 μg/l in 205 out of 273 (76.2%) supplies sampled. The mean of the positive values was approximately 24 μg/l, with a range of 5–164 μg/l. The above data include the Rural Water Survey (RWS) for which the validity of the lead data have been questioned. Excluding the RWS, the values are:

Source	Percent positive (> 5 μg/l)	Mean of positives	Range
Ground water	76.3 (539/706)	13 μg/l	5–182 μg/L
Surface water	64.0 (100/119)	14 μg/l	5–32.5 μg/L

Compliance monitoring data for the Interim Regulations indicate that 66 public water supplies (59 ground water and 7 surface water) were reported to exceed the current MCL of 50 μg/l. Fourteen of the ground water supplies and 3 of the surface water supplies had levels above 150 μg/l.

Health Effects. The health effects of lead in both humans and animals are generally measured by relating blood lead (PbB) levels to adverse effects. Numerous studies have been carried out in which PbB levels of people across the United States have been measured, and these levels correlated with adverse effects. This type of measurement has not been done for most other chemicals, where the effects are described in terms of concentration of intake of the chemical. For the purpose of deriving an RMCL, the PbB levels at which adverse effects occur will be evaluated, and these levels will be related to lead levels in drinking water.

As discussed elsewhere in recent EPA assessments of the health effects of lead (Quantification of Toxicological Effects of Lead for Drinking Water; U.S. EPA, 1984. Air Quality Criteria for Lead), the most serious effects associated with markedly elevated blood lead levels are severe neurotoxic effects that include irreversible brain damage, as indexed by the occurrence of acute or chronic encephalophatic symptoms; for most adults such damage typically does not occur until PbB levels exceed 100–120 μg/dl (Kehoe, R.A. 1961a. The Metabolism of Lead in Man in Health and Disease: the Normal Metabolism of Lead (The Harben Lectures, 1960). J.R. Inst. Public Health Hyg. 24, 129–143; Smith, F.L., Rathmell, T.K., Marcil, G.E. 1938. The Early Diagnosis of Acute and Latent Plumbism. Am. J. Clin. Pathology). Often associated with encephalopathic symptoms at such PbB levels are severe gastrointestinal symptoms and objective signs of effects on several other organ systems. Precise threshold(s) for occurrence of overt neurological and gastrointestinal signs and symptoms of lead exposure in cases of subencephalopathic lead intoxication remain to be established, but such effects have been observed in adult lead workers at PbB levels as low as 40–60 μg/dl. Other types of health effects occur coincident with the above overt neurological and gastrointestinal symptoms indicative of marked lead intoxication. These range from frank peripheral neuropathies to chronic nephropathy and anemia.

Toward the lower range of blood lead levels associated with overt lead intoxication (Quantification of Toxicological Effects of Lead in Drinking Water; U.S. EPA, 1984. Air Quality Criteria for Lead), less severe but important signs of impairment in normal physiological functioning in several organ systems are evident among apparently asymptomatic lead-exposed adults, including: (1) Slowed nerve conduction velocities indicative of peripheral nerve dysfunction (at PbB levels as low as 30–40 μg/dl) (Seppalainen, et al. 1975. Subclinical Neuropathy at "Safe" Levels of Lead Exposure. Arch. Environ. Health 30:180–183); (2) altered testicular function (at 40–50 μg/dl) (Lancranjan, et al. 1975. Reproductive Ability of Workmen Occupationally Exposed to Lead. Arch. Environ. Hlth. 30:396–401); and (3) reduced hemoglobin production (at approximately 50 μg/dl) (Zielhuis, R.L. 1975. Dose-Response Relationships for Inorganic Lead. I. Biochemical and Haematological Responses. Int. Arch. Occup. Environ. Health. 35:1–18), and other signs of impaired heme synthesis evident at still lower PbB levels. All of these effects point toward a generalized impairment of normal physiological functioning across severa different organ systems, which becomes evident as adult PbB levels exceed 30–40 μg/dl. Evidence for impaired heme synthesis effects in blood occur at even lower PbB levels in adults.

New research findings demonstrating a relationship between blood lead levels and increases in blood pressure have appeared in the published literature (Harlan, et al. 1985. Blood Lead and Blood Pressure, JAMA. 253:530–534; Pirkle, et al. 1985. The Relationship Between Blood Lead Levels and Blood Pressure and its Cardiovascular Risk Implications. Am. Journ. Epid. 21:246–258). A preliminary review of this work indicates a statistically significant correlation between blood lead levels and diastolic blood pressure in white males, ages 40–59, with no threshold apparent in the range of 6–30 μg/dl. Possible increases in risk of more severe medical events (stroke, heart attack, death) associated with lead-induced increases in blood pressure are also estimated in one of the recently published analyses (Pirkle, et al. 1985. The Relationship Between Blood Lead Levels and Blood Pressure and its Cardiovascular Risk Implications. Am. Journ. Epid. 21:246–258).

Children represent a sensitive subpopulation with regard to lead toxicity. As with adults, lead affects many different organ system and biochemical/physiological process across a wide range of exposure levels. Effective blood levels for producing encephalopathy or death in children are lower than for adults, starting at approximately 80–100 μg/dl. Permanent, severe mental retardation and other marked neurological deficits are among lasting neurological sequelae typically seen in cases of nonfatal childhood lead encephalopathy. Other overt neurological signs and symptoms of subencephalopathic lead intoxication are evident in children at lower PbB levels (e.g., peripheral neuropathies detected in some children at levels as low as 40–60 μg/dl). Chronic nephropathy, indexed by aminoaciduria, is most evident at high exposure levels over 100 μg/dl, but may also exist at lower PbB levels (e.g., 70–80 μg/dl). In addition, colic and other overt gastrointestinal symptons clearly occur at similar or lower PbB levels in children, at least down to 60 μg/dl.

Frank anemia is also evident by 70 μg/dl, representing an extreme manifestation of reduced hemoglobin synthesis observed at PbB levels as low as 40 μg/dl, along with other signs of marked heme synthesis inhibition at that exposure level. All of these effects are reflective of the widespread marked impact of lead on the normal physiological functioning of many different organ systems; some are evident in children at PbB levels as low as 40 μg/dl, and all are widely accepted as clearly adverse health effects.

Additional studies demonstrate evidence for further, important health effects occurring in non-overtly lead intoxicated children at similar or lower blood lead levels than those indicated above. Among the most important and controversial of these effects are neuropsychological and electrophysiological effects evaluated as being associated with low-level lead exposures in non-overtly lead-intoxicated children. None of the available studies on CNS effects, individually, can be said to prove conclusively that significant cognitive (IQ) or behavioral effects occur in children at PbB levels <30 μg/dl. Rather, the collective neurobehavioral studies of CNS cognitive (IQ) effects can probably now most reasonably be interpreted as being indicative of likely associations between neuropsychologic deficits in young children and PbB levels ranging as low as 30–50 μg/dl, and of possibly some small risk at somewhat lower levels (15–30 μg/dl).

Also of considerable importance are studies which provide evidence of changes in EEG brain wave patterns and CNS evoked potential responses in non-overtly lead intoxicated children. Research results demonstrate clear, statistically significant associations between electrophysiological (SW voltage) change and PbB levels in the range of 30–55 μg/dl and analogous associations at PbB levels below 30 μg/dl (with no evident threshold down to 6 μg/dl) (Otto, 1981. Effects of Age and Body Lead Burden on CNS Function in Young Children. I: Slow Cortical Potentials. Electroencephalogr. Clin. Neurophysiol. 52:229–239). In this case, the presence of electrophysiological changes observed upon follow-up of some of the same children two and five years later suggests persistence of such effects even in the face of later declines in PbB levels and, therefore, possible long-term persistence of the observed electrophysiological CNS changes (Otto, 1984. Five year follow-up study of children with low to moderate lead absorption: electrophysiologic evaluation. Presented at: Second International Conference on Prospective Lead Studies, April. Cincinnati, OH). However, the reported electrophysiological effects in this case were not found to be significantly associated with IQ decrements and in general, the medical significance of many of the electrophysiological alterations induced by low-level lead exposure remains to be elucidated. However, the effects on auditory brainstem evoked potentials observed across the range of PbB levels of 6 and 59 μg/dl may be an indication of subtle neurological impairment (Otto, et al., 1984).

Research concerning lead-induced effects on heme synthesis also provides information of the importance in evaluating what blood lead levels are associated with significant health effects in children. Lead affects heme synthesis at several points in its metabolic pathway, with consequent impact on the normal functioning of many body tissues. The activity of the enzyme ALA–S, catalyzing the rate-limiting step of heme synthesis, does not appear to be significantly affected until PbB levels reach or exceed approximately 40 μg/dl. However, inhibition of the enzyme ALA–D, which catalizes the conversion of ALA to porphobilinogen as a further step in the heme biosynthetic pathway, has been observed in humans and other mammalian species at PbB levels even below 10–15 μg/dl, with no clear threshold evident. Correlations between erythrocyte and hepatic ALA–D activity inhibition in lead workers at PbB levels in the range of 12–56 μg/dl suggest that ALA–D activity in soft tissues (e.g., brain, liver, kidney, etc.) may be inhibited at similar PbB levels at which erythrocyte ALA–D activity inhibition occurs, resulting in accumulations of ALA in both blood and soft tissues.

Lead also affects heme synthesis beyond metabolic steps involving ALA, leading to the accumulation of porphyrin in erythrocytes as the result of impaired iron insertion into the porphyrin moiety to form heme. The prophyrin acquires a zinc ion in lieu of the native iron, and the resulting accumulation in blood of zinc protoporphyrin (ZPP) tightly bound to erythrocytes for their entire life (120 days) represents a commonly employed index of lead exposure for medical screening purposes. The threshold for elevation of erythrocyte protoporphyrin (EP) levels is well-established as being 25–30 μg/dl in adults and approximately 15 μg/dl for young children.

Recently, it has also been demonstrated in children that lead is negatively correlated with circulating levels of the vitamin D hormone, 1,25-dihydroxyvitamin D, with no evident threshold, down to 12 μg/dl of PbB (Rosen, J.F. 1984. Metabolic and Cellular Effects of Lead: A Guide to Low Level Lead Toxicity in Children. In: Mahaffey, K.R. ed. Dietary and Environmental Exposure to Lead. In press; Mahaffey, et al. 1982. Association Between Age, Blood Lead Concentration and serum 1,25-Dihydroxycholecalciferol Levels in Children. Am. J. Clin. Nutr. 35:1327). This effect of lead is of considerable significance on two counts: (1) Altered levels of 1,25-$(OH)_2$-vitamin D not only impact calcium homeostasis (affecting mineral metabolism, calcium as a second messenger and calcium as a mediator of cyclic nucleotide metabolism), but also likely impact its known role in immuno-regulation and mediation of tumorigenesis; and (2) the effect of lead on 1,25-$(OH)_2$-vitamin D is a particularly robust one, with PbB levels of 30–50 μg/dl resulting in decreases in the hormone that overlap comparable degrees of decrease seen in severe kidney injury or certain genetic diseases (Rosen, J.F. 1983. The Metabolism of Lead in Isolated Bone Cell Populations: Interactions Between Lead and Calcium. Toxicol. Appl. Pharmacol. 71:101; Rosen, J.F. and R.W. Chesney. 1983. Circulating Calcitriol Concentrations in Health and Disease. J. Pediatr. (St. Louis) 103:1).

Erythrocyte Py-5-N activity in children has also been demonstrated to be negatively impacted by lead at exposures resulting in blood lead levels markedly below 30 μg/dl (i.e., to levels below 10 μg/dl with no evident threshold). Extensive reserve capacity exists for this blood enzyme, such that it is not markedly depleted until PbB levels reach approximately 30–40 μg/dl, arguing for the Py-5-N effect in and of itself as perhaps not being particularly adverse until such blood lead levels are reached. However, the observation of Py-5-N inhibition is more arguably indicative of wider-spread impacts on pyrimidine metabolism in general (i.e., in additional organs and tissues besides blood), such that lead exposures lower than 30 μg/dl resulting in measurable Py-5-N inhibition in erythrocytes may be of greater medical concern when viewed from this broader perspective.

In addition to the above health effects in adults and children, experimental evidence exists for carcinogenic activity (renal tumors) associated with oral ingestion of high doses of lead in at least one mammalian species (i.e., the rat) and some cases of renal tumors in long-exposed human lead workers. The issue

of lead carcinogenicity remains to be resolved in light of the other more extensive epidemiology studies which did not detect increased tumor incidence among lead-exposed human populations. The IARC have classified lead in Group 3; inadequate evidence for carcinogenicity to humans, sufficient evidence of carcinogenicity to animals (for some salts), inadequate evidence for activity in short-term tests. Lead has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment based upon evidence of kidney tumors in rats by the oral route. However, the dosages that induced the kidney tumors in rats were very high (beyond the lethal dose in humans) and several extensive epidemiology studies did not show an association between lead exposure and increased tumor incidences in occupationally exposed workers. In view of the above issues, the RMCL for lead will not be set based upon carcinogenic endpoints, instead other sensitive endpoints will be the basis.

The current MCL for lead, under the National Interim Primary Drinking Water Regulations, is 0.05 mg/l. This level was based upon an estimation that this level in drinking water would contribute 25 to 33 percent of the lead normally ingested for a child and 33 percent of that in food for an adult.

The NAS (*Drinking Water and Health*, 1984 Vol. V) has stated that the current drinking water standard of 0.050 mg/l may not, in view of other sources of environmental exposure, provide a sufficient margin of safety, particularly for fetuses and young growing children. The WHO guidelines for drinking water (1984) suggest that lead should not exceed 0.050 mg/l. This level was based upon a provisional tolerable weekly intake of 3 mg of lead per person established in 1972 by the Joint FAO/WHO Expert Committee on Food Additives. Assuming a drinking water lead level of 0.050 mg/l, the 3 mg weekly intake would not be exceeded even with a daily diet containing 0.3 mg of lead and the WHO concluded that this allowed for some margin of safety. New data indicate that adverse health effects from lead occur at lower blood lead levels than believed in 1972 when the tolerable weekly intake was established.

EPA's ambient water quality criteria (U.S. EPA, 1980. Ambient Water Quality Criteria for Lead. EPA 440/5-80-057) for human health, which considers ingestion of water and contaminated aquatic organisms, is 0.050 mg/l. This value was based upon an analysis which concluded that the present drinking water standard of 0.050 mg/l may be viewed as representing the upper limit of acceptability.

Short-term assessments have not been determined for lead because, other than in cases of acute exposures to rather high lead levels, it generally takes a sustained exposure to lead for many days to produce body lead levels capable of inducing adverse effects.

At blood lead levels below 30 μg/dl, many of the different effects reported as being associated with lead exposure might be argued as separately not being of clear medical significance, although each are indicative of interference by lead with normal physiological processes. On the other hand, the collective impact of all of the observed effects (representing potentially impaired functioning and depleted reserve capacities of many different tissues and organs) may, at some point distinctly below 30 μg/dl, be seen as representing an adverse pattern of effects worthy of avoidance with some added margin of safety. The onset of signs of detectable heme synthesis impairment in many different organ systems, indications of increasing degrees of pyrimidine metabolism interference, signs of altered nervous system activity, and interference in vitamin-D metabolism start appearing at PbB levels around 10–15 μg/dl. All of these effects could be viewed as becoming sufficiently adverse to warrant avoidance when the various effects come to represent marked deviations from normal as PbB levels exceed 20–25 μg/dl.

An additional concern is one recent report that an increase of 5 μg/l in the blood lead levels produced a concomitant increase in diastolic blood pressure of approximately 2 mm Hg in white males, ages 40–59.

If one assumes that infants consuming formula reconstituted from tap water are the most sensitive subpopulation under consideration, and that a blood lead concentration of 15–20 μg/dl is the level of concern, it is possible to calculate the lead level in drinking water at which this group would be at risk. If 15 μg/dl were selected as the level of concern and using a conversion factor of 6.25 to convert from PbB to lead in drinking water (Ryu, et al. Dietary Intake of Lead and Blood Lead Concentration in Early Infancy. Am. J. Dis. Child. 137:886–891), the following calculation can be made: 15 μg/dl × 6.25 = 94 μg/l, (assuming consumption of 1 liter of water per day). Several alternatives are available in terms of the application of an uncertainty factor. One alternative is to assume an uncertainty factor of five, which would correspond to a drinking water lead level of 20 μg/l, if drinking water were the sole source of exposure. An uncertainty factor of five could be assumed instead of the traditional factor of 10 for human studies, since extremely subtle effects in a sensitive subpopulation (infants and children) were the endpoints upon which the level of concern was selected. A second alternative consists of applying an uncertainty factor of 10, resulting in a drinking water lead level of 10 μg/l.

A second option consists of using 20 μg/dl as the level of concern, converting this blood lead level to drinking water lead as was done in the first option (resulting in 125 μg/l), and applying an uncertainty factor. If an uncertainty factor of 10 was applied, this would correspond to a drinking water lead level of 13 μg/l. A second alternative consists of applying an uncertainty factor of 5, corresponding to a drinking water lead level of 25 μg/l.

A third option would be to set the RMCL at zero, since the health effects seen are often extremely subtle effects that may not have a threshold.

Exposure to lead results in effects on the nervous system, hematopoietic system and other physiological processes. Due to these effects and the significant occurrence potential in drinking water, EPA is proposing to continue to regulate lead. EPA is proposing an RMCL of 0.020 μg/l based upon the effects of lead in infants as a sensitive subpopulation. Comments are requested on all of the issues outlined below and on the additional options proposed for setting the RMCL.

Questions for Comment:

1. Is it most appropriate to base the RMCL upon a single health effect endpoint, or a constellation of effects?

2. What uncertainty factor should be included in setting the RMCL for lead?

3. To what extent should possible carcinogenic effects of lead be taken into account as a margin of safety consideration?

4. What is the most appropriate model to relate blood lead levels with drinking water levels?

5. Are women of child bearing age, the developing fetus, the neonate or the one to three year old child the most sensitive subpopulation(s)?

6. Which of the options presented for developing an RMCL for lead is most appropriate given currently available knowledge about lead health effects and exposures?

8. Mercury

Mercury exists in two basic forms: the inorganic salt and organic mercury

compounds (methyl mercury). Mercury levels in coal range from 10–46,000 ppb, through generally it is in the range of 200–400 ppb, with soil concentrations ranging from 30–300 ppb. Most of the known areas with substantially elevated mercury in geologic materials are found in California, Nevada, Oregon and Washington.

The major use of mercury is in electrical equipment (batteries, lamps, switches, and rectifiers). It is also used in the chloralkali industry as a flowing cathode for electrolytic deposition of salt brine into chlorine, sodium hydroxide and hydrogen.

Mercury may also enter the environment from mining, smelting, and fossil fuel combustion. Natural processes such as volcanic activity, geothermal activity and volatilization from mineral deposits result in mercury entering the atmosphere.

Analytical Methods. Analytical methods available for analyzing mercury in drinking water include the manual cold vapor and automated cold vapor techniques.

Human Exposure. Mercury is introduced into the air from both natural and anthropogenic sources. Ambient levels of mercury range between 10–20 ng/m^3. In areas near coal-fired power plants, levels be as high as 1000 ng/m^3. Usually high concentrations of 10,000–15,000 ng/m^3 have been reported near rice fields where mercury fungicides have been, used and in the vicinity of mercury mines.

The average daily absorption of atmospheric mercury for an adult male is estimated to be approximately 320 ng, based upon an average atmospheric concentration of 20 ng/m^3, a ventilation rate of 20 m^3 and the assumption that 80 percent of the inhaled rate is absorbed.

Food is a primary source of exposure to mercury, and the major dietary source appears to be the consumption of fish. The FDA estimated the dietary intake of mercury to be 4.3 μg/day for the adult male (excluding beverages), of which 3.8 μg comes from meat, fish, and poultry categories.

Almost all mercury detected to date in drinking water is in the form of inorganic mercury. Compliance monitoring indicates that 12 ground water and 11 surface water supplies have reported levels above 2 μg/l. All of the ground water supplies serve less than 5,000 people whereas five of the surface water supplies serve more than 10,000 people.

There is only limited federal survey data on mercury. Of 106 ground water supplies sampled between 1978 and 1980, 32 (30%) were found to have levels above 0.5 μg/l, and 14 (13%) were found to have levels above 2 μg/l. In surface water supplies, mercury was observed at levels of 0.5 μg/l in 10 out of 31 supplies sampled (32%), with 5 supplies (16%) at levels above 2 μg/l. It is not clear why the federal surveys suggest a substantially higher frequency of occurrence above 2 μg/l than is indicated by the compliance monitoring results. The major source of federal survey data was the Rural Water Survey.

Health Effects. Inorganic mercury is poorly absorbed through the gastro-intestinal tract, does not penetrate cell membranes rapidly and is less toxic than methyl mercury. The principal target organ of inorganic mercury is the kidney. Methyl mercury compounds exert their toxicologic effect on the central nervous system. Contamination of fish and shellfish by methyl mercury compounds has resulted in Minamata Disease in Japan, characterized by mental disturbances, ataxia, disturbance in speech and hearing impairment.

Short-term assessment values were not calculated for mercury due to insufficient data. A provisional AADI was calculated for inorganic mercury based upon a study (Druet, et al. 1978. Immune Type Glomerulonephritis Induced by Mercuric Chloride in the Brown Norway Rat. Ann. Immunol. 129C:777–792) in which rats were exposed to inorganic mercury salts for 8 to 12 weeks through subcutaneous injection. The primary endpoints evaluated were antibody formation and proteinuria, with proteinuria seen at doses of 100 μg/kg and above, but not at 50 μg/kg. In the 50 μg/kg exposure group, a total of 36 doses totalling 1800 μg/kg were injected over the 84-day period. The NOAEL was determined to be 50 μg/kg/day and a factor of 0.739 to adjust for the percentage by weight of mercury in mercuric chloride was included in the development of the provisional AADI. An uncertainty factor of 1000 was applied because proteinurea, an adverse health effect, occurred at concentrations of mercury only twice the NOAEL. To compensate for the difference in absorption between subcutaneous and oral exposure, an absorption factor of 10 was used, resulting in a provisional AADI of 0.0055 mg/l. This value was based upon inorganic mercury because almost all mercury in drinking water is thought to be in the form of inorganic mercury.

The IARC have not evaluated the carcinogenic potential of mercury. Mercury has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data in animals and humans.

The WHO guideline (1984) for mercury in drinking water is 0.001 mg/l and applies to all chemical forms of mercury. This level was based upon the determination that 2 liters of water containing 0.001 mg/l mercury would normally contribute less than 10 percent of the tolerable intake of mercury. EPA's ambient water quality criterion (U.S EPA. 1980. Ambient Water Quality Criteria for Mercury. EPA 440/5–80–058) for human health considering ingestion of water is 0.000144 mg/l. This was based upon the ingestion of water and contaminated aquatic organisms which contain methyl mercury.

Exposure to inorganic mercury compounds at high levels results in renal effects. Because inorganic mercury is the form of mercury detected in drinking water, has widespread occurrence and may have adverse health effects, a revised regulation is proposed. An RMCL for inorganic mercury of 0.003 mg/l is proposed, based upon a provisional AADI of 0.0055 mg/l with data on human exposure factored in (0.0043 mg/day via the diet and 0.001 mg/day via air).

Question for Comment:

1. Should a separate RMCL be proposed for organic mercury compounds?

9. Nitrate and Nitrite

Nitrate is the more stable oxidized form of combined nitrogen in most environmental media. Most nitrogenous materials in natural waters tend to be converted to nitrate, and, therefore, all sources of combined nitrogen (particularly organic nitrogen and ammonia) should be considered as potential nitrate sources. Nitrates occur naturally in mineral deposits (generally sodium or potassium nitrate), in soils, seawater, freshwater systems, the atmosphere and in biota. Lakes and other static water bodies usually have less than 1.0 μg/l of nitrate/nitrogen. (Generally, the occurrence of nitrate is measured and reported in terms of its nitrogen content; 1.0 μg/l of nitrate/nitrogen is equivalent to 4.4 μg/l of nitrate.) Ground water levels of nitrate/nitrogen may range up to 20 μg/l or more, with higher levels characteristically occurring in shallow aquifers beneath areas of extensive development. Major sources of nitrates or nitrite in drinking water include fertilizer, sewage and feedlots.

Analytical Methods. Analytical methods available for analyzing nitrate and nitrite in drinking water include the colorimetric brucine spectrometric cadmium reduction, automated

hydrazine reduction and automated cadmium reduction techniques.

Human Exposure. A daily respiratory intake ranging from 25 to 70 μg/day based upon reported urban and nonurban levels of nitrogen oxides has been determined.

Food is generally recognized as the major source of nitrate intake. The estimated dietary intake is approximately 100 μg/day, with 85 to 90 percent coming from vegetables and 9 percent from cured meats. Most vegetables contain nitrate. Beets, celery, lettuce, radishes, and spinach were reported to have levels ranging from 120 to 635 ppm (dry weight). Much lower levels (10–24 ppm) were reported for tomatoes, potatoes and peas.

Compliance monitoring indicates that approximately 570 community public water supplies are providing water with nitrate/nitrogen levels above 10 μg/l (44 μg/l nitrate).

Three national surveys conducted between 1969 and 1980 indicated that 835 out of 1,479 (56%) ground water supplies had nitrate/nitrogen levels above 0.3 μg/l (nitrate levels of 1.32 μg/l). The mean nitrate/nitrogen levels above 0.3 μg/l was 1.8 μg/l, and values ranged up to about 22 μg/l. There were 20 ground water supplies with levels above 10 μg/l (1.4%).

In these same surveys, nitrate/nitrogen levels of 0.3 μg/l were found in 175 out of 409 surface water supplies sampled (42.8%), with a mean value of 1.8 μg/l. The nitrate/nitrogen values in surface water ranged up to 21 μg/l. There were 5 supplies (1.2%) with levels above 10 μg/l. The presence of nitrite in drinking water at significant levels is unusual and would indicate probable organic contamination (i.e., sewage), lack of disinfection (reducing conditions) and probable bacterial contamination.

Health Effects. The toxicity of nitrate in humans is due to the body's reduction of nitrate to nitrite. This reaction takes place in saliva of humans at all ages and in the gastrointestinal tract of infants during the first three months of life. The toxicity of nitrite is demonstrated by vasodilatory/cardiovascular effects at high dose levels and methemoglobinemia at lower dose levels. Methemoglobinemia is an effect in which hemoglobin is oxidized to methemoglobin, resulting in asphyxia.

Infants up to 3 months of age are the most susceptible subpopulation with regard to nitrate. This is due to the fact that in the adult and child, about 10 percent of ingested nitrate is transformed to nitrite, while 100 percent of ingested nitrate can be transformed to nitrite in the infant.

The effects of methemoglobinemia are rapidly reversible and there are, therefore, no accumulative effects. There are no suitable data for calculating one-day assessment values for either nitrate or nitrite. However, the ten-day assessment values for both nitrate and nitrite will be protective for one-day exposures.

A study by Craun, et al. (1981) was selected as the basis for calculating ten-day assessment values for nitrate in adults. Craun, et al. (1981) observed that nitrate levels up to 111 μg/l nitrate/nitrogen did not produce methemoglobin in one to eight year old children. The data of Craun, et al. (1981) are appropriate to use as the basis for a ten-day adult assessment of 111 μg/l nitrate-nitrogen because the child and the adult would be expected to have similar responses to nitrate. An uncertainty factor was not employed in the derivation of the number since the most sensitive subpopulation, infants, are considered separately and would not need to be protected under this number.

The ten-day adult assessment for nitrite can be calculated using the ten-day nitrate assessment and assuming a 10 percent conversion of nitrate to nitrite. Thus, the ten-day assessment for nitrite in adults is 11 μg/l nitrite nitrogen.

As the provisional AADI for both nitrate and nitrite is based upon short-term exposure in the infant, it is appropriate to use the provisional AADI as a 10-day assessment for the infant.

A provisional AADI was calculated for nitrate/nitrogen based upon the infant (4 kg) as a high risk subpopulation. The study used was an epidemiologic study in which 300 cases of infant methemoglobinemia were surveyed (Walton, G. 1951. Survey of Literature Relating to Infant Methemoglobinemia due to Nitrate Contaminated Water. Am. J. Pub. Health 41:986–966). No cases were associated with drinking water containing less than 10 μg/l of nitrate/nitrogen. Using 10 mg/l as a NOAEL, without the application of an uncertainty factor (large number of subjects exhibiting no signs of toxicity), a provisional AADI of 10 mg/l was determined for nitrate/nitrogen. This value would also be protective for the infant for short-term exposures (1- and 10-days). For nitrite/nitrogen, the same study was used, with an uncertainty factor of 10 applied to the NOAEL (10 mg/l), due to the demonstrated direct toxicity of this chemical, resulting in a provisional AADI of 1 mg/l. This value would also be protective for the infant for short-term exposures (1- and 10-days).

Many studies have demonstrated that nitrate/nitrite administered with nitrosatable compounds are carcinogenic in animals. However, the carcinogenic potential of nitrate/nitrite when administered in the absence of nitrosatable compounds has not been demonstrated. The IARC have not classified nitrate/nitrite for potential carcinogenicity. Nitrate/nitrite have been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data in animals and humans.

The current MCL for nitrate/nitrogen, under the National Interim Primary Drinking Water Regulations, is 10 mg/l. This level was based upon human case studies in which fatal poisonings in infants have occurred following ingestion of well waters containing nitrate concentrations greater than 10 mg/l nitrate/nitrogen.

The WHO guidelines are 10 mg/l for nitrate/nitrogen and 1 mg/l for nitrite/nitrogen. The basis is that undesirable increases in methemoglobin levels in blood occur at levels from 10 mg/l to 20 mg/l nitrate and the ingestion of nitrite leads to a more rapid onset of clinical effects and thus the guideline value should be correspondingly lower (1 mg/l).

Nitrate/nitrite compounds have demonstrated adverse toxic effects in infants. Due to potential toxicity and wide spread occurrence in water, revised drinking water regulations will be proposed. The RMCL will be based upon non-carcinogenic effects and RMCLs of 10 mg/l for nitrate/nitrogen and 1 mg/l for nitrite/nitrogen are proposed. Data on human exposure were not factored in the RMCL because the provisional AADI was based upon an epidemiologic study in which exposure via the air and diet is already taken into account.

Questions for Comment:

1. Should the carcinogenic potential of nitrosatable compounds influence the proposed RMCLs for nitrate/nitrogen and nitrite/nitrogen? If so, how?

2. The Criteria Document on Nitrate/Nitrite outlines an alternate methodology for calculation of short-term assessment values. Is this an appropriate approach for calculation of these numbers?

3. What uncertainty factors should be applied in the calculation of the AADIs for nitrate and nitrite?

10. Selenium

Selenium occurs in U.S. soils at concentrations ranging from 0.03 to 0.8 ppm with very little difference between

the soils of eastern and western States. However, in the western States, the more alkaline soils tend to make selenium more water soluble and increased plant uptake and accumulation occurs. Sedimentary rocks have higher concentrations of selenium than do igneous rocks. Of the sedimentary rocks, shales frequently contain more selenium than limestones or sandstones.

Most of the commercial selenium produced in the U.S. is recovered from copper ores. Only 256 metric tons were produced in 1981; an additional 338 metric tons were imported. The reported consumption of selenium for 1981 was for electronic and photocopy applications, glass manufacture, pigments, chemicals, pharmaceuticals, fungicides and as feed additives. Selenium releases to the environment result from coal (coal contains 1.6–3.3 ppm) burning, non-ferrous mining and smelting, and the remainder from selenium refining, glass manufacture and fuel oil combustion (1970 estimate).

Analytical Methods. Analytical methods available for analyzing selenium in drinking water include the gaseous hydride atomic absorption, furnace atomic absorption and inductively coupled plasma atomic emission spectrometry techniques.

Human Exposure. In general, selenium levels in the air in the U.S. appear to be below 5 ng/m³. One study showed that levels near a coal-fired power plant, a major source of selenium to air, were <3 ng/m³. Three reportd estimates of daily rspiratory intake of selenium are 0.02, 0.07 and <1 μg.

The selenium content of foods ranges from undetected or trace levels (<0.001 ppm) to approximately 1.0 ppm. Higher levels (0.2–1.0 ppm) are reported for the meat, fish, poultry, and grains and cereal food classes. A recent FDA market basket survey reported that dietary intake for the adult male was 152 μg/day, of which 52 percent comes from grains and cereals, 36 percent from meat, fish and poultry and 10 percent from dairy products. Other studies have reported selenium intake through the diet ranging from 80 to 150 μg/day (*Drinking Water and Health*, 1980. Vol. III; Welsh, et al. 1981. Selenium in Self-Selected Diets of Maryland Residents. Jour. Am. Dietic Assn. 79:277–285).

Compliance monitoring indicate that 150 ground water and 6 surface water supplies contain selenium levels above 10 μg/1.

In the 1969 Community Water Supply Survey (CWSS), 654 out of 671 ground water supplies (97%) had selenium at levels ranging from 1 μg/1 to 65 μg/1 (mean of the positives was 2.7 μg/1). In the 1978 CWSS, 12 out of 258 ground water supplies (4.7%) had levels above 5 μg/1 and 2 (0.8%) had levels above 10 μg/1. In the Rural Water Survey (RWS), 30 out of 71 ground water supplies (42.3%) had levels above 5 μg/1 and 8 out of 71 (11.3%) had levels above 10 μg/1.

The 1969 CWSS reported that selenium was found in all 106 surface water supplies sampled, at levels ranging from 1.0 to 10 μg/1 (mean value, 4.6 μg/1). In the 1978 CWSS, none of the 94 supplies sampled were found to have measurable levels of selenium; the minimum quantifiable levels ranged from 2.5 to 5 μg/1. In the RWS, 2 out of 21 surface supplies had levels above 5 μg/1.

Health Effects. Selenium has toxic effects at high dose levels and is nutritionally essential at low levels. Acute and chronic toxic effects have been observed in animals. In humans, little data exists on acute toxicity, while a recently completed study on endemic selenium intoxication in humans in China (Yang, G., et al. 1983. Endemic Selenium Intoxication of Humans in China. Amer. Jour. Clin. Nutr. 37:872–881) reported that chronic toxicity was observed in individuals consuming a daily average of 4.8 mg selenium through the diet, with a minimum selenium intake of 3.2 mg.

In animals, selenium deficiency results in congenital white muscle disease and other diseases. A level of 0.1 mg Se/kg food has been considered to be the general level of dietary requirements in animals. Selenium is considered to be an essential element for human nutrition, with an approximate intake level of 100–200 μg/day adequate to prevent deficiency in a 70 kg adult. The NAS (*Drinking Water and Health*, 1980. Vol. III) have estimated an adequate and safe intake of selenium for adults of 0.05 to 0.20 mg/day with correspondingly lower intakes for children and infants.

A 1-day assessment was not calculated for selenium due to insufficient data. The values calculated for the 10-day levels are considered protective for the 1-day exposure period. A 10-day assessment for the adult was calculated based upon a study (Halverson, et al. 1966. Toxicity of Selenium to Post-weanling Rats. Toxicol. Appl. Pharmacol. 9:477–484) in which rats were fed sodium selenite for 6 weeks and levels of 4.8 mg/kg feed (0.41 mg/kg/day) produced no adverse effects as compared with controls. A 10-day assessment for the adult of 144 μg/1 was determined, using 0.41 mg/kg day as the NOAEL, an uncertainty factor of 100 based upon an animal study and consumption of 2 liters of water per day. A 10-day assessment for the child of 45 μg/1 was calculated based upon the same study, assuming consumption of 1 liter of water per day.

A provisional AADI was calculated based upon a human study (Yang, et al. 1983. Endemic Selenium Intoxication of Humans in China. Amer. Jour. Clin. Nutr. 37:872–881) which examined selenium toxicity and deficiency effects in China. The minimum daily selenium intake level in an area of chronic selenosis was reported to be 3.20 mg. A provisional AADI of 0.106 mg/1 was calculated using 3.20 mg/day as a LOAEL, consumption of two liters of water per day and an uncertainty factor of 15. This uncertainty factor was applied to a human study with a great deal of data. An uncertainty factor of 10 would traditionally be applied, however in this instance an uncertainty factor of 15 was applied due to data which suggests that selenium ingested in food may be absorbed less efficiently than selenium ingested in water. This information would support the use of an uncertainty factor greater than 10.

Naturally occurring selenium compounds (selenate and selenite) have not been shown to be carcinogenic in animals. On the contrary, many studies have shown these selenium compounds to result in the inhibition of tumors of various types, including tumors of the skin, liver, mammary glands, colon and lung. Selenium sulfide, a manufactured product not normally found in water, was found to be positive in the National Cancer Institute bioassay by gavage (NCI, 1980. Bioassay of Selenium Sulfide (gavage) for Possible Carcinogenicity. NCI Technical Support Series No. 194, NTP No. 80–17). The IARC has not classified selenium for potential carcinogenicity. Selenium has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assesment, based upon inadequate data in animals and humans.

The current MCL for selenium, under the National Interim Primary Drinking Water Regulation, is 0.01 mg/1. This level was based upon signs of selenium toxicity at an intake of 0.7–7 mg/day and an assumed selenium intake of 200 μg/day.

The WHO guideline (1984) for selenium is 0.01 mg/1. The WHO stated that current estimates of selenium intake range between 130 and 200 μg/day and the maximum daily selenium intake from drinking water should not exceed 10 percent of the recommended maximum daily dietary intake of 200 μg. Assuming an intake of 2 liters of water per day, the WHO determined a

guideline value of 0.01 mg/1. EPA's ambient water quality criteria (U.S. EPA. 1980. Water Quality Criteria Document for Selenium. EPA 440/5–80–070) for human health is 0.010 mg/1 in agreement with the NIPDWR. Current data suggests that selenium is an essential nutrient and has anti-carcinogenic effects in animals. These guidelines (WHO and ambient water quality criteria) did not take the beneficial effects of selenium into account.

Selenium exposure at high levels results in chronic adverse health effects. EPA is proposing to continue regulation of selenium because of its potential adverse health effects and widespread occurrence. An RMCL of 0.045 mg/1 is proposed, based upon a provisional AADI of 0.106 mg/1, with data on human exposure factored in (0.125 mg/day via the diet).

Questions for Comment:

1. Does the proposed RMCL for selenium reflect an adequate balance between the toxicity and deficiency effects of the compound?

2. It is more appropriate to apply a traditional uncertainty factor of 10 for selenium, resulting in an RMCL of 97 μg/1?

C. IOC's for Which RMCLs Are Not Proposed

1. Aluminum

Aluminum is the third most abundant element in the earth's crust and occurs most commonly as aluminosilicates, such as clay, kaolin, mica and feldspar and as bauxite or cryolite. Uses of aluminum compounds and alloys include production of aircraft, utensils, and electrical conductors. The metal powder is used in explosives, pigments, paints and coatings and putties. Aluminum compounds (e.g., aluminum sulfate) are commonly used in drinking water treatment for coagulation.

Analytical Methods. Analytical methods available for analyzing aluminum in drinking water include the flame atomic absorption, furnace atomic absorption and inductively coupled emission spectrometry techniques.

Human Exposure. Levels of elemental aluminum in the ambient air over the continental U.S. have been reported to range from 0.14–8.0 ug/m³. Levels of aluminum in metropolitan areas were an order of magnitude greater than those in rural areas. Background atmospheric concentrations have been measured from 0.005–0.032 ug/m³.

Aluminum is naturally present in nearly all foods. Other significant sources of the metal in the diet are baking powder, food additives, antacids, and dietary supplements. In addtion, aluminum cookware, utensils and storage containers can be sources of the metal in foods. Numerous studies are available on dietary intake of aluminum reported levels ranging from less than 1.53 to as much as 100 mg/day. The average adult intake from the diet, however, is calculated to be approximately 20 mg aluminum per day.

Aluminum commonly occurs in finished drinking water supplies, especially surface waters treated with alum. Use of this compound can increase (or decrease) the level of aluminum in finished waters.

In a recent EPA study (1983) of the occurrence of aluminum in drinking water, an analysis was conducted of randomly selected community water systems. Levels of aluminum (mg/1) in finished drinking water determined for various types of water systems and sizes are shown below:

	Levels	Median
Ground Water—no coagulant	0.014–0.290	0.031
Surface Water—no coagulant	0.016–1.167	0.043
Surface Water—Alum coagulant	0.014–2.670	0.112
Surface Water—Iron coagulant	0.015–0.061	0.036

Median aluminum levels (mg/1) by population category (both ground water and surface water) were as follows:

Number of individuals served	Concentrations of aluminum	
	Median	Overall median
25 to 999	<0.014–0.031	<0.014
10,000 to 99,999	<0.014–0.264	0.023
100,000 to 999,999	<0.014–0.236	0.045
>1,000,000	<0.014–0.082	0.033

A review of earlier surveys of finished drinking water supplies across the U.S. (1962, 1969, 1977) indicates mean levels of aluminum ranging from 0.073–0.104 μg/l. Levels of the metal in individual samples ranged from 0.003–2.4 μg/l.

Health Effects. In general, aluminum is considered to possess low acute toxicity for the normal individual following oral exposure. Oral LD_{50}s for aluminum chloride in several animal species ranged from 380 to 780 mg/kg. Few data exist from animal studies following subchronic or long-term oral exposure. These suggest primarily that effects may be seen at relatively high doses on phosphorus balance, and that the adverse sequelae are, in fact, the result of this change (e.g., osteomalacia). No evidence of fetotoxicity or teratogenicity has been observed in animals following oral exposure. On the other hand, there is a report of decreased sperm count and motility in rats exposed to 2.5 mg/kg by gavage for 6 months. Studies to evaluate the potential of aluminum or its salts to induce mutagenic or carcinogenic effects have yielded negative results.

In the human, deposition of aluminum in the brain has been suggested as an etiological factor in the neurologic disorders, Alzheimer's disease and dialysis dementia in patients with chronic renal failure. This hypothesis has not been confirmed and the question of the relationship between aluminum and certain neurological disorders is one that is receiving a great deal of attention by the medical research community at the present time. In addition, the Agency is pursuing lines of investigation in experimental studies which should shed light on the dose-response relationships in animals following exposure to aluminum salts in drinking water. Since, at the present time, there are no adequate dose-response data available from which to estimate an AADI for ionic aluminum in drinking water, EPA is proposing not to establish an RMCL and primary regulation. Aluminum will be reevaluated at a later date, after the results of the animal studies become available.

A guidance level of 0.05 mg/l is recommended for aluminum such that treatment is fully effective in removing coagulated materials to avoid setting of particles in the distribution system. This value is not based upon health and has been recommended by the American Waters Works Association as a goal for potable water. The WHO has recommended a guideline value of 0.2 mg/l based upon water discoloration.

2. *Cyanide.* Cyanides are organic or inorganic compounds that contain the cyanide moiety, —CN. Organic compounds having this functional group are referred to as nitriles. Cyanides are formed readily in many industrial processes and can be found in a variety of effluents. Cyanide commonly occurs in water as hydrocyanic acid (HCN), the cyanide ion (CN^-), simple cyanides, metallocyanide complexes or as simple chain and complex ring organic molecules.

Cyanide production in the U.S. in 1978 exceeded 700 million pounds. The major industrial users of cyanide in the U.S. are the producers of steel, plastics, synthetic fibers and chemicals and the electroplating and metallurgical industries. In addition to these industries, cyanide wates are discharged into the environment from the pyrolysis of a number of synthetic and natural materials and from chemical, biological, and clinical laboratories. Cyanide in drinking water is oxidized by chlorine at basic pH to cyanate.

Analytical Methods. Analytical methods available for analyzing cyanide in drinking water include colorimetric and automated electrode techniques with distillation.

Human Exposure. No information is available on levels of cyanide in the ambient air.

No data are available on the occurrence of cyanide in foods. Except for certain naturally occurring nitriles in plants, it is unlikely that cyanide would be found in foods of the U.S.

Cyanide is relatively uncomon in most U.S. water supplies. In 2,595 water samples, the Community Water Supply Survey (CWSS) of 969 U.S. public water supply systems in 1970 revealed the highest cyanide concentration found was 8 μg/l and the average concentration was 0.09 μg/l. However, cyanide has been found in surface waters and is present in waste waters. It is soluble in water and used in large quantities across the country. Although it is biologically and chemically degradable, it has appeared in some drinking water systems.

Health Effects. Cyanides are readily absorbed from the lungs, the gastro-intestinal tract and the skin by animals and humans. The toxic effects of cyanide occur due to the combination of cyanide with cytochrome in the cell, with resulting hypoxia. Cyanide may be detoxified in the liver by rhodanese, an enzyme in the liver which metabolizes cyanide to form a less toxic compound, thiocyanate. The major route of cyanide elimination from the body is via urinary excretion of thiocyanate.

No suitable data were identified for the calculation of a one-day assessment. Although there are data available to calculate the 10-day assesment value, it is recommended that the 1-day and 10-day levels be set at the AADI of 0.75 mg/l for the 70 kg adult consuming 2 liters of water per day. Using the same data base, the 1-day and 10-day assessment value for the 10 kg child consuming 1 liter of water is calculated to be 220 μg/l.

A provisional AADI was calculated based upon a two-year study in which rats were administered diets containing 0, 100 or 300 mg/kg hydrogen cyanide (Howard, J.W. and Hanzel, R.F. 1955. Chronic Toxicity for Rats of Food Treated with Hydrogen Cyanide. J. Agric. Food Chem. 3:325:329). Average doses due to volatilization were calculated to be 76 mg/kg/diet hydrogen cyanide (73 mg/kg/diet cyanide) for the low dose group and 167 mg/kg/diet hydrogen cyanide (160 mg/kg/diet cyanide) for the high dose group. The estimated daily doses were 3.6 and 4.6 mg/kg body weight cyanide for the low-dose males and females, respectively, and 7.5 and 10.8 mg/kg body weight cyanide for the high dose males and females, respectively. At these dose levels, no treatment-related toxic effects including histopathologic lesions were observed. A provisional AADI of 0.75 mg/l cyanide was calculated from the NOAEL of 10.8 mg/kg cyanide with an uncertainly factor of 500 (an additional uncertainty factor of 5 was included because cyanide was given in the diet rather than in drinking water) and assuming human consumption of 2 liters of water per day.

Potassium cyanide was negative for mutagenicity in *Salmonella typhimurium* and *Bacillus subtilis*. The IARC have not classified cyanide for potential carcinogenic effects. Cyanide has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data in animals and humans.

The WHO guideline for drinking water is 0.1 mg/l. This value was based upon 4.7 mg cyanide/day which has been recorded to not be harmful to humans. Assuming consumption of 2 liters of water per day, the WHO concluded that cyanide concentrations of 2.35 mg/l could be consumed in water. Allowing for a safety factor, the WHO considered a guideline value of 0.1 mg/l to be reasonable. EPA's ambient water quality criteria (U.S. EPA. 1980. Ambient Water Quality Criteria for Cyanide. EPA 440/5–80–037) for human health considering ingestion of water and contaminated aquatic organisms is 0.2 mg/l. This value was updated (February 1984. 49 FR 4551) and the proposed revised value is 3.77 mg/l based upon the same study used to derive the provisional AADI. The difference in the two numbers is due to the addition of an additional uncertainty factor of 5 in the derivation of the provisional AADI since cyanide was given in the diet rather than drinking water.

Cyanide has rarely been detected in drinking water supplies, and when it has been detected it has been at levels so far below the provisional AADI that an RMCL for cyanide would almost certainly be useless. Thus, EPA has decided not to propose an RMCL for cyanide at the present time.

Questions for Comment:

1. Are there sufficient health effects and exposure information upon which to base an RMCL?

2. Is the assumption of 100 percent contribution from drinking water reasonable?

3. Is it appropriate to apply an additional uncertainty factor of 5 to account for the absorption differences between cyanide exposure via food and drinking water?

4. Should EPA set an RMCL for cyanide despite the fact that it has been detected at levels far below the provisional AADI?

3. Molybdenum

Molybdenum occurs naturally as molybdenum sulfide and as molybdenite salts. Uses include the manufacture of special steel for tools, boiler plate, and propeller shafts, tungsten, x-ray tubes, filaments and non-ferrous alloys. Molybdenum is also used as an additive in lubricants.

Analytical Methods. The analytical methods available for analyzing molybdenum in drinking water are the flame atomic absorption, furnace atomic absorption and inductively coupled plasma atomic emission spectrometry techniques.

Human Exposure. Molybdenum is considered an essential trace element in humans. The NAS has estimated the dietary intake of molybdenum to range from 0.1 to 0.46 mg/day. In a separate study, an average daily intake of 0.18 mg/day was estimated based on an analysis of 300 samples of 40 different foods, collected from 5 supermarkets over a 3-year period.

In an early study (1964) of finished water supplies of the 100 largest cities in the United States, levels of molybdenum were reported to range from not detected to 68 μg/l (median=1.4 μg/l). In a later 5-year study (1970) of 380 finished waters, 29.9% had measurable levels of molybdenum; concentrations ranged from 3 to 1,024 μg/l (mean=85.9 μg/l). Results of a recent and extensive study (1978) of tap waters of the U.S. showed molybdenum in 30 percent of the samples, with levels ranging from 1.1 to 52.7 μg/l (mean=8.0 μg/l). According to the NAS, molybdenum in drinking water, except from highly contaminated sources (e.g., molybdenum mining wastewater) is not likely to constitute a significant portion of the total human daily intake of the element.

Health Effects. Molybdenum is readily absorbed through the gastrointestinal tract, with the highest concentrations in the liver, kidneys and bone. There is no apparent bioaccumulation of molybdenum in animal or human tissues. A steady state concentration is reached when intake is increased, and when the dose is withdrawn, tissue concentrations return to normal levels. The principal route of excretion is via the urine.

Acute toxic effects from exposure to molybdenum consists of damage to the

liver, kidneys and sometimes adrenals and spleen. Ruminants are more sensitive to molybdenum than are monogastric animals. Subchronic toxic effects in animals consist of a decreased growth rate, male infertility, weight loss and bone or joint abnormalities in forelegs.

Molybdenum is an essential element at low doses and has toxic effects at high dose levels. The NAS (*Drinking Water and Health*, 1980, Vol. III) have estimated an adequate and safe intake level of 0.15 to 0.50 mg/day for adults and children 11 years and older.

One-day assessments of 2.7 mg/l (child) and 9.5 mg/l (adult) have been calculated for molybdenum based upon a study (Fairhall, et al., 1945. The Toxicity of Molybdenum. Pub. Hlth. Serv. Bull.) in which a single intraperitoneal dose of 20 mg molybdenum (80 mg/kg ammonium molybdate) did not show any apparent effects. Other studies have shown that the LD^{50} for orally ingested ammonium molybdate is about three times higher than for molybdenum trioxide and calcium molybdate, the forms commonly found in water. Thus, a NOAEL of 27 mg/kg was used, calculated by dividing the NOAEL for ammonium molybdate (80 mg/kg) by three to account for the potential differential toxicity. An uncertainty factor of 100 was applied based upon a NOAEL from an animal study, with an assumed water consumption of 1 liter per day (child) and 2 liters per day (adult).

Sufficient data were not available from which to derive 10-day assessments. Ten-day numbers were calculated by dividing the 1-day numbers by 10, resulting in values of 0.27 and 0.95 mg/l for children and adults, respectively.

A provisional AADI was calculated for molybdenum based upon a human study (Chappell, W.R., et al., 1979. Human Health Effects of Molybdenum in Drinking Water. Cincinnati, OH. U.S. EPA–600A–79–006) in which blood molybdenum levels were within normal ranges and no adverse effects were noted when drinking water levels were 0.200 mg/l or less. Using 0.200 mg/l as a NOAEL, an uncertainty factor of 2 based upon a human study with no adverse effects noted and consumption of 2 liters of water per day, a provisional AADI of 0.10 mg/l was determined. Data on human exposure were not factored in the AADI because the calculations were based upon an epidemiological study in which exposure via other sources were necessarily taken into consideration.

The only molybdenum compound that has been shown to produce tumors in animals is an inorganic pigment which contains a lead chromate, sulfate and molybdenum compound. This compound was shown to produce tumors by subcutaneous injection; however since both lead and chromate are present in the compound it is possible that the effect was due to these metals and not molybdenum. The IARC have not classified molybdenum for potential carcinogenicity. Molybdenum has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data in animals and humans.

The WHO has not recommended a limit for molybdenum in drinking water. The NAS also has not recommended a level of molybdenum in drinking water other than the safe intake level for nutritional effects. According to the NAS (1980), "Our understanding of chronic molybdenum toxicity or deficiency is presently extremely limited. This topic should be studied. Further studies should also be conducted to determine the interaction of molybdenum with other elements and nutrients in humans."

EPA has decided not to propose an RMCL at this time for molybdenum because of the inadequate data on toxicity of the compound. A provisional AADI of 0.10 mg/l was determined based upon an epidemiological study in which only one dose was examined and no effects were noted. This study did not determine at what level effects may have been seen. Animal studies examining chronic toxicity are not available and thus an AADI could not be calculated based upon these effects. Acute animal studies are available but acute studies are not an adequate basis for determining an AADI.

Question for Comment:

1. Should a Health Advisory be developed for molybdenum or is there sufficient health effects information upon which to base an RMCL?

4. Nickel

Elemental nickel is not commonly found in nature as the pure metal, but occurs as sulfides, arsenides, antimonides, and oxides or silicates. The pure metal is very low in solubility. Nickel salts and many nickel compounds, however, are soluble. In the aquatic environment, nickel is most likely to occur as a divalent cation and may often absorb to or complex with mineral or organic compounds.

The major use of nickel is in the manufacture of stainless steel, nickel-chrome resistance wire and in alloys for electronic and space applications.

Analytical Methods. Analytical methods available for anaylzing total nickel in drinking water include the flame atomic absorption, furnace atomic absorption and inductively coupled plasma emission spectrometry techniques.

Human Exposure. Levels of nickel in the ambient air of 237 urban and 47 nonurban localities in the U.S., for the period 1970 to 1974, were determined by EPA. Arithmetic means for each of these years ranged from 0.009 to 0.015 $\mu g/m^3$ for urban areas and 0.002 to 0.001 $\mu g/m^3$ for nonurban areas (detection limit, 0.001 $\mu g/m^3$). For any given year, the urban values were 3 to 4 times that of the nonurban areas.

Reported dietary levels of nickel for U.S. consumers range from 165 to 900 μg/day. Average values range from 400 to 500 μg/day. Nickel is common in a wide variety of foods. Food processing methods, however, may add additional levels through leaching from stainless steel processing equipment.

A summary of levels of nickel in 380 U.S. drinking water supplies for the years 1962 to 1967 was prepared by the U.S. Department of Interior. Levels of nickel ranged from 1 to 490 $\mu g/l$, with a mean of 34.2 $\mu g/l$. The frequency of detection was 4.6 percent.

Levels of nickel have been reported for 969 public water supplies in 8 metropolitan areas for the years 1969 to 1970. The average value was 4.8 $\mu g/l$ and the maximum was 75 $\mu g/l$.

Health Effects. The absorption of dietary nickel from the gastrointestinal tract appears to be quite low with the majority of nickel excreted in the feces. Laboratory studies have demonstrated depressed body weight gain, alterations in hematology parameters, cytochrome oxidase activity and iron contents of organs following high dose oral exposure.

Insufficient data are available for the derivation of 1-day assessments for nickel. The available short-term (1–15 days) toxicity studies of nickel using the oral route of exposure reported only acute effects (LD_{50}).

The 10-day assessments for the 10 kg child and 70 kg adult were based on an animal study (Whagner, 1973. Effects of Dietary Nickel on Enzyme Activities and Mineral Content in Rats. Toxicol. Appl. Pharmacol. 25:323–331). From a NOAEL of 10 mg Ni/kg/day based on effects on weight, hematologic parameters and cytochrome oxidase activity in rats following 6 week oral ingestion, with an uncertainty factor of 100, assuming consumption of 1 liter (10 kg child) or 2 liters (70 kg adult) of water per day, 10-day values for a child and an adult of 1.0 mg Ni/l and 3.5 mg Ni/l, respectively, were calculated.

A provisional AADI was calculated based upon a two-year feeding study in which rats were given various doses of nickel in their food (Ambrose, A.M., et al. 1976. Long Term Toxicological Assessment of Nickel in Rats and Dogs. J. Food Sci. Technol. 13:181–187). Based on a number of parameters (body weight, organ-to-body weight ratios, hematologic values, gross and histologic pathology), this study revealed a NOAEL of 5 mg Ni/kg day. A disadvantage of this study is that nickel was given in food, and absorption of metals from the gastrointestinal tract may be decreased by the presence of food (Rabar, I. and Kostial, K. 1981. Bioavailability of Cadmium in Rats Fed Various Diets. Arch. Toxicol. 47:63–66; Foulkes, E. 1984. Nickel Absorption Studies in Rats; preliminary report). Using a NOAEL of 5 mg/kg/day, an uncertainty factor of 100, an absorption efficiency of 0.20 (assumed difference in absorption of nickel in food vs. water) and consumption of 2 liters of water per day, a provisional AADI of 0.350 mg/l was calculated. The available data indicate that the estimated intake of nickel from food and air are 400 μg/day and 0.6 μg/day (negligible) respectively. Factoring in this data on human exposure, a guidance level of 0.150 mg/l has been determined.

Two other studies investigating the effects of nickel ingestion on reproduction in rats (Ambrose, A.M., et al. 1976; Schroeder, H.A. and Mitchner, M. 1971. Toxic Effects of Trace Elements on the Reproduction of Mice and Rats. Arch. Environ. Health 23:102–106) were not selected for the derivation of an AADI for nickel due to several experimental design flaws.

Nickel chloride was negative for mutagenicity in *Escherichia coli* and *Bacillus subtilis*, while nickel chloride and nicket sulfate have been shown to be mutagenic in eukaryotic test systems.

The chemical form and route of exposure are important factors in determining the carcinogenic potential of nickel. Metallic nickel, nickel subsulfide and nickel carbonyl which are insoluble nickel compounds, have been shown to produce tumors through inhalation exposure in animals. Intravenous injection of nickel carbonyl has also been shown to result in liver and kidney sarcomas in animals. In humans, it has been demonstrated that the incidence of respiratory tract cancers in nickel refinery workers is significantly elevated. However, nickel has not been shown to be carcinogenic through oral exposure. The results of several studies suggest that 5 mg/l nickel in drinking water is not carcinogenic in rats and mice. Data are not available concerning the potential carcinogenic effects of ingested nickel compounds in humans. The IARC has classified nickel in Group 2A: sufficient evidence for carcinogenicity in animals and limited evidence for carcinogenicity in humans. This assessment was based upon inhalation exposure. Nickel has been classified in EPA's Group B1, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon the subsulfide and carbonyl compounds which have been shown to have limited evidence of carcinogenicity in humans and sufficient evidence in animals.

EPA's ambient water quality criteria for nickel (U.S. EPA. 1980. Ambient Water Quality Criteria for Nickel. EPA 440/5–80–060) considering ingestion of water and contaminated aquatic organisms is 0.0134 mg/l. This value was revised (February 1984. 49 FR 4551) and the proposed revised value is 0.632 mg/l based upon the same study which was used to determine the provisional AADI.

EPA has decided not to propose drinking water regulations for nickel due to inadequate toxicological data. Data problems with the provisional AADI and the data base on nickel include: (a) lack of data on the absorption of nickel; (b) lack of data on reproductive effects; and (c) the study by Ambrose, et al. (1976) requires additional statistical analyses.

Question for Comment:

1. Should a Health Advisory be developed for nickel, or are there sufficient health effects information upon which to base an RMCL?

5. Silver

Silver is a relatively rare metal with average concentrations in the earth's crust ranging from 0.07 to 0.08 ppm. In soils, the average concentration is 0.1 ppm; coal can contain slightly elevated silver concentrations, typically ranging from about 0.1 to 2 ppm. Silver is recovered primarily from gold-silver and silver-lead deposits. Background levels of silver in surface water are generally below 3 μg/l.

The major commercial uses of silver are in photography, electric/electronic components, sterling and electroplate, and alloys and solder. Environmental releases can occur during ore mining and processing, product fabrication and disposal. However, because of the great economic value of silver, recovery practices are typically used to minimize losses.

Analytical Methods. Analytical methods available for analyzing silver in drinking water include the flame atomic absorption, furnace atomic absorption and inductively coupled plasma atomic emission spectrometry techniques.

Human Exposure. There are little data on silver levels in air. Silver in ground level aerosols from various U.S. locations was found to range from 0.04 to 4.3 ng/m^3, generally ranging around 1 ng/m^3. Assuming a ventilation rate of 20 m^3/day for the adult male, respiratory intake at levels of 1 ng/m^3 would be approximately 0.02 μg/day.

The silver content of various foods has been reported to range from <10 ppb in meats to 2 ppm in seafood. The ICRP estimated the dietary intake of silver for the adult male to be 70 μg/day (including fluids).

Compliance monitoring indicate that 12 ground water supplies and one surface water supply have silver levels above 50 μg/l. Drinking water data are also available on silver from three national surveys. In the 1969 Community Water Supply Survey (CWSS), silver was found in 309 out of 677 ground water supplies (46%) at levels ranging from 0.1 to 9 μg/l. In the 1978 Community Water Supply Survey (CWSS), silver was observed in 8 out of 81 ground water supplies (10%); however, the minimum quantifiable levels was 30 μg/l. Positive values ranged from 30 to 40 μg/l. In the Rural Water Survey (RWS), silver was found in 8 out of 71 supplies sampled (11%) with a range of positive values from 20 to 80 μg/l; the minimum quantifiable level for the RWS was 20 μg/l.

In surface water supplies, silver was observed in the 1969 CWSS in 59 out of 109 supplies sampled (54%) at values ranging from 0.1 to 4 μg/l. In the 1978 CWSS, silver was found to range from 0.04 to 4.3 ng/m^3, generally ranging around 1 ng/m^3.

Point of use water treatment devices containing silver impregnated granular activated carbon could be the principal source of silver in drinking water at the consumer's tap.

Health Effects. The only adverse effect resulting from chronic exposure to low levels of silver in animals and humans is argyria, a blue-gray discoloration of the skin and internal organs. Argyria is markedly disfiguring and is a permanent, non-reversible effect. Argyria is the result of silver deposition in the dermis and at basement membranes of the skin and other internal organs.

One-day and 10-day assessments were not calculated for silver due to inadequate data. A provisional AADI was determined based upon several clinical reports in which humans developed argyria as a result of i.v. and oral exposure to silver (Gaul and Staud,

1935. Clinical Spectroscopy. Seventy Cases of Generalized Argyrosis Following Organic and Colloidal Silver Medication. J. Am. Med. Assoc. 104:1387–1390; Blumberg, H. and T.N. Carey. 1934. Argyremia: Detection of Unsuspected and Obscure Argyria by the Spectrographic Demonstration of High Blood Silver. J. Am. Med. Assoc. 103:1521–1524; and East, et al. 1980. Silver Retention, Total Body Silver and Tissue Silver Concentration in Argyria Associated with Exposure to an Anti-smoking Remedy Containing Silver Acetate. Clin. Exp. Dermatol. 5:305–311). Calculations were carried out to determine the level of silver in drinking water, apportioned over a lifetime, which would not result in argyria. The average ADI of the calculations from the 3 studies was determined to be 182 μg/day (average of 109 μg/day and 168 μg/day). This was calculated by standardizing the observed body weight to the 70 kg adult and multiplying this by the estimated total dose necessary to cause argyria and apportioning this over a lifetime (70 years). An uncertainty factor of two was used instead of the standard 10-fold uncertainty factor for the following reasons: the 10–fold uncertainty factor is applied to humans to account for possible sensitive individuals in the general population. The studies used in the ADI calculations involved sensitive individuals and thus an uncertainty factor less than 10 is warranted. In addition, the ADI calculations are extremely conservative because the estimated dose which caused argyria in 2 to 3 years is being apportioned over a lifetime of 70 years. An uncertainty factor less than 10 would be sufficiently protective in this instance. Consumption of 2 liters of water per day was factored in, resulting in a provisional AADI of 0.090 mg/l.

There is no evidence that exposure to silver results in mutagenic or carcinogenic effects. The IARC have not classified silver for potential carcinogenicity. Silver has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data in animals and humans.

The current MCL for silver, under the National Interim Primary Drinking Water Regulations, is 0.05 mg/l. This level was based upon one gram of silver resulting in argyria. EPA's ambient water quality criteria for silver (U.S. EPA. 1980. Water Quality Criteria for Silver. EPA 440/5–80–071) is 0.050 mg/l, in agreement with the NIPDWR. The WHO has not set a guideline for silver in drinking water.

The only adverse effect from exposure to silver is argyria, which does not impair the functioning of the body or other physiological problems. Thus, argyria is considered a cosmetic effect and not an adverse health effect and an RMCL is not proposed.

Question for Comment:

1. Is it appropriate to consider argyria to be a cosmetic effect or is there evidence that argyria is an adverse health effect? Should an RMCL be proposed for silver? Should a secondary regulation be proposed for silver?

6. Sulfate

Sulfate (SO^{2-}) is a divalent anion found in almost all natural waters. It also occurs frequently in rainfall, particularly from air masses of metropolitan areas where sulfate is released from combustion of fossil fuels. An important terrestrial source is evaporite sediment, from which magnesium, sodium and calcium sulfate may be leached. Metallic sulfides such as iron pyrites are found in both sedimentary and igneous rocks. Sulfates are released through oxidation in the weathering process. Household waste including detergents add sulfate to sewage. Industrial effluents from tanneries, steel mills, sulfate-pulp mills, and textile plants are other significant sources to surface water.

Human Exposure. Data on levels of sulfate in the ambient air are available from EPA's Office of Air Quality Planning and Standards. A summary of atmospheric concentrations (1975) for selected locations in the U.S. is presented below.

	Number of samples	Concentration SO_4 ($\mu g/m^3$)	
		Arithmetic mean	Maximum
California (Oakland)	25	4.5	10.3
Ohio (Cincinnati)	28	13.3	33.8
Texas (Lubbock)	18	5.0	25.4
Virginia (Richmond)	28	12.5	27.5

Data were not available on the occurrence of sulfate in foods.

The CWSS, conducted in 1970, examined 969 drinking water supplies in the U.S. Levels of sulfate were reported to range from <1 to 770 mg/l (median=4.6 mg/l). Of the sampled water supplies, 3 percent had concentrations exceeding 250 mg/l. Analysis of the interstate carrier water supply systems (1975) involved examination of 625 finished drinking water supplies. In 3.4 percent of the sampled systems, levels of sulfate exceeded 250 mg/l. The maximum measured concentration was 978 mg/l.

Analytical Methods. Analytical methods available for analyzing sulfate in drinking water include the turbidimetric and automated colorimetric techniques.

Health Effects. The only adverse effects in animals and humans noted from exposure to high levels of sulfate are diarrhea and dehydration. Soluble sulfate salts are absorbed from the intestine and distributed throughout the body, with large doses being incompletely absorbed, resulting in cathartic effects. Sulfate is continuously excreted in the urine.

In humans, the concern is for transient situations as individuals will become acclimated to high levels of sulfate in a short period of time and diarrhea and dehydration do not occur after the initial acclimation period. Infants appear to be more sensitive to sulfate than adults, with several cases of diarrhea and gastroenteritis reported in infants consuming formula containing sulfate at levels ranging from 630–1150 mg/l.

In areas of the country with high sulfate concentrations in their drinking water supplies, no adverse health effects in older children and adults have been associated with exposure to sulfate over lifetime exposure. In addition, insufficient toxicological data are available to calculate an AADI based upon short-term effects in adults or infants. Thus, a provisional AADI will not be calculated for sulfate. Instead, a guidance level of 400 mg/l, to protect infants, was derived based upon case histories which suggest that parents should not use water from wells with sulfate concentrations greater than 400 to 500 mg/l for preparation of infant formula.

In addition, 250 mg/l is presented as a guidance level based upon aesthetic considerations. This value would serve to limit the intake and protect the high risk population (infants).

The current EPA secondary drinking water standard for sulfate is 250 mg/l based upon aesthetic effects. The WHO guidline for sulfate is 400 mg/l based upon taste considerations. The U.S. Army has recommended limits for sulfate of 300 or 100 mg/l, based upon personnel who consume up to 15 liters of water per day (100 mg/l) and those who consume up to 5 liters of water per day (300 mg/l) (Scofield, R. and Hsieh, D. Criteria and Recommendations for Standards for Sulfate in Military Field Water Supplies. Univ. of Calif.).

An RMCL and primary drinking water regulations will not be developed for sulfate as there are not sufficient data at the present time on which to set a level for health protection. However,

exposure to sulfate at high levels does present a health concern for transient exposure situations and EPA will reconsider an RMCL in the future based upon new data and research results, as available.

Question for Comment:

1. It is appropriate to derive an advisory for sulfate based upon the high risk population or should an RMCL be developed?

7. Sodium

Sodium (atomic number 11, atomic weight 22.99) is a light silvery-white alkali metal that composes 2.38 percent (by weight) of the earth's crust. Sodium does not occur as the free element in nature but in the form of halides, silicates, and carbonates. Sodium is the principal cation in the hydrosphere. It is derived geologically from the leaching of surface and underground deposits of salts (e.g., sodium chloride) and from the decomposition of sodium aluminum silicates and similar minerals.

Analytical Methods. Analytical methods for analyzing sodium in drinking water include the direct aspiration atomic absorption, furnace atomic absorption and flame photometry.

Human Exposure. While there is considerable information on the sodium content of foods, few studies are available of total daily sodium-ion intake for healty adults. Data that have been reported are based on measurement of sodium excretion in urine over 12 and 24 hour periods. Reported mean 24-hour levels range from 1,600 to 9,600 mg. A recent estimate for infants is 69 to 92 mg/kg/day.

The sodium ion is a major constituent of natural waters. Human activities also contribute sodium to water supplies, primarily through the use of sodium chloride as a deicing agent, and the use of washing products. A survey of 2,100 finished water supplies was conducted from 1963 to 1968 by the U.S. Public Health Service. Levels of sodium ion were found to range from 0.4 to 1,900 mg/l. Of the supplies having sodium ion concentrations, 42 percent exceeded 20 mg/l. Levels in 5 percent of the supplies were greater than 250 mg/l. In a later study (1975) of interstate carrier water supply systems, sodium ion concentrations in 630 systems were found to range from <1 to 402 mg/l. A total of 42 percent had levels exceeding 20 mg/l; 3 percent had levels greater than 200 mg/l.

Health Effects. The first epidemiologic study of the relationship of sodium in drinking water and blood pressure in the United States was undertaken by Calabrese and Tuthill (1977. Elevated Pressure and High Sodium Levels in the Public Drinking Water. 32:300–302; Ibid. 1979. 34:197–203). These investigators compared blood pressure distributions among tenth graders in two Massachusetts communities exposed to low (8 mg/l) and high (107 mg/l) levels of sodium in drinking water. Students living in the high-sodium community exhibited higher blood pressures than their counterparts in the low-sodium community. In the Netherlands (Hofman, et al. 1980. Increased Blood Pressure in School Children Related to High Sodium Levels in Drinking Water. J. Epidemiol. Comm. Hlth. 34:179–181), a study reported findings which supported the hypothesis that sodium intake influences blood pressure.

Various epidemiologic studies that failed to confirm an association between drinking water sodium and blood pressure also have been reported (Pomrehn, et al. 1983. Community Differences in Blood Pressure Levels and Drinking Water Sodium. Am. J. Epidemiol. 118:60–71; Punsar, et al. 1975. Coronary Heart Disease and Drinking Water. J. Chron. Dis. 28:259–287; Bierenbaum, et al. 1975. Possible Toxic Water Factor in Coronary Heart Disease. Lancet. 1:1008–1010; Hallenbeck, et al. 1981. High Sodium in Drinking Water and Total Sodium Intake on Blood Pressure. Am. J. Epidemiol. 114:817–826; Faust, 1982. Effects of Drinking Water and Total Sodium Intake on Blood Pressure. Am. J. Clin. Nutr. 35:1459–1467; Armstrong, et al. 1982. Water Sodium and Blood Pressure in Rural School Children. Arch. Environ. Hlth. 37:235–245). Willett assessed epidemiologic data relating to the hypothesis that sodium in drinking water causes a clinically significant elevation of blood pressure among school children in Massachusetts and concluded that the data should be interpreted with extreme caution (1981. Drinking Water Sodium and Blood Pressure: A Cautious View of the 'Second Look'. Am. J. Pub. Hlth. 71:729–732). Based on the available studies, it appears that insufficient evidence is available to conclude whether or not sodium in drinking water causes an elevation of blood pressure in the general population.

It has been estimated that food accounts for approximately 90 percent of the daily intake of sodium whereas drinking water contributes up to the remaining 10 percent.

In order to afford protection to a segment of the U.S. population on a sodium-restricted diet, in 1968, the American Heart Association (AHA) recommended a level of 5 mg of sodium per 8 ounces of water or 20 mg/l. The basis for AHA's recommended level of sodium was a nutritionally adequate diet requiring 500 mg sodium per day. Of the 500 mg, 440 mg would be naturally occurring in food. An additional 60 mg would be from non-nutritional intake such as drugs, water, and incidential intake sources.

In 1976, the National Interim Primary Drinking Water Regulations did not contain an MCL for sodium because the available data did not support any particular level of sodium in drinking water. In lieu of the absence of an MCL for sodium, EPA supported the AHA's recommended level of 20 mg sodium/l in drinking water. In 1980, EPA amended the National Interim Primary Drinking Water Regulations, requiring community water systems to monitor and report sodium levels in finished drinking water.

EPA is not proposing an RMCL for sodium due to insufficient data showing an association between sodium in drinking water and hypertension in the general population and because of the normally minor contribution of drinking water to the total dietary intake of sodium. EPA is suggesting a guidance level for sodium of 20 mg/l in drinking water for the high risk population as recommended by the AHA, since drinking water meeting this goal would not present a sodium-related hazard to those segments of the population thought to be at high risk (e.g., individuals with genetic predisposition to hypertension, pregnant women, hypertensive patients). EPA will reconsidered the development of an RMCL for sodium if additional data become available. A secondary standard based upon aesthetic effects will be prepared for sodium.

Questions for Comment:

1. Are there sufficient data available to develop an RMCL instead of a health advisory for sodium in drinking water?

2. Does the proposed health advisory for sodium provide protection to high risk populations?

8. Antimony, Beryllium, Thallium and Vanadium

Antimony, beryllium, thallium and vanadium were included in the list of IOCs under consideration for Revised Regulations in the ANPRM. Preliminary analysis indicated limited potential for drinking water exposure causing a significant risk from these substances. Data collection efforts on occurrence/human exposure and potential health effects have not yet been completed on these substances and these four IOCs will be considered in later Phases of the Revised Regulations.

9. Zinc

Zinc was also included in the list of IOCs under consideration for Revised Regulations in the ANPRM. The Agency has not identified any adverse health effects that are caused by zinc. The NAS Safe Drinking Water Committee (*Drinking Water and Health*, 1977, Vol. I) concluded that, "zinc is an essential nutrient for humans. There is evidence of borderline deficiencies of the element in children in the United States as well as in other parts of the world . . . . The possibility of detrimental health effects arising from zinc consumed in food and drinking water is extremely remote."

Thus, EPA has concluded that potential adverse health effects will not arise from zinc in drinking water and this compound is not being considered for regulation at the present time.

VIII. Synthetic Organic Chemicals: RMCL's

The ANPRM (48 FR 45502) listed a total of 43 synthetic organic chemicals (SOCs) that were being considered for inclusion in the NPDWR. Inclusion of specific SOCs on the list was based upon the occurrence or potential occurrence of the SOC in drinking water and the potential health effects of exposure to that SOC. Inclusion in the list did not necessarily mean that regulations would be developed for the SOC but that those were the SOCs currently being considered; other SOCs not listed could also be considered and included in the NPDWR. Selection of SOCs for the NPDWR is based upon an analysis of occurrence and potential occurrence, the significance of potential human exposure, associated health effects of exposure and other pertinent factors.

EPA is today proposing to regulate 26 of the 43 SOCs in the ANPRM; five of the SOCs were determined to be inappropriate for regulation due to such factors as lack of potential occurrence in drinking water, lack of actual occurrence data, or insufficient health effects data. Short- and longer-term toxicology assessments have been developed for those five SOCs for which regulations are not appropriate; these assessments may be converted to formal Health Advisories. In addition, 12 SOCs of the 43 SOCs will be reconsidered in later phases of the Revised Regulation development as additional data become available (see Table 1).

RMCLs are proposed for 26 SOCs for which the Administrator has determined that: (1) Analytical methods are available, (2) exposure to any of these SOCs "may have any adverse effect upon the health of persons" and, (3) they occur or are likely to occur in drinking water.

Below are: (1) A summary of the availability of analytical methods, and (2) summaries per SOC of analytical methods, occurrence/exposure and toxicology.

In the MCL proposal, EPA will propose the analytical methods that have been determined to be economically and technologically feasible. In the toxicology discussion for each SOC, the acute and chronic toxic effects of exposure along with any carcinogenicity data are summarized. When data are available, adjusted acceptable daily intakes (AADIs) based on non-carcinogenic effects are determined for long term exposure to the SOCs. In addition, short-term exposure is also considered and short-term assessments are determined for 1-day and 10-day exposures. These assessments are provided for both SOCs for which RMCLs are proposed and for those SOCs for which regulations do not appear to be appropriate. A summary of health-related guidelines prepared by other groups and organizations is provided for each SOC. Values that have been calculated by the World Health Organization (WHO), the National Academy of Sciencies (NAS), EPA's Office of Water Regulations and Standards (OWRS, Water Quality Criteria) and EPA's Office of Pesticide Programs (OPP) have been included. In several instances, these values differ from the proposed AADIs. This is due to several factors, including the use of different uncertainty factors, and reinterpretation of data and varying assumptions. In addition, new data may have become available over the years which has resulted in the derivation of an AADI which differs from older calculated values. Taste and odor threshold values also have been included for certain contaminants.

A summary of the RMCLs and AADIs is presented in Table 12. Risk estimates have been projected using calculation models for SOCs for which data are available and are summarized in Table 13. Short-term assessments and provisional AADIs for SOCs for which RMCLs are not proposed are summarized in Table 14 and short-term assessments for SOCs for which RMCLs are proposed are summarized in Table 15.

A. Availability of Analytical Methods

EPA approved analytical methods are available for most of the SOCs being considered in this RMCL proposal. These methods may involve gas chromatography (GC), gas chromatography/mass spectrometry (CG/MS), and and high pressure liquid chromatography (HPLC).

Purge and trap methods are available for those SOCs that are volatile. Those compounds which are methylene chloride extractable may be analyzed by 600 series methods (i.e., EPA methods for analysis of priority pollutants). Other compounds may be analyzed by newer methods developed recently but not yet approved by the Agency.

Since a number of the 600 series methods have been recently applied to drinking water samples in addition to waste effluent samples, multi-laboratory method validation data are available for many of the compounds in this proposal. Multi-laboratory data from performance evaluation studies are also available for some compounds, using reagent water. For the newer methods, only single laboratory, single operator performance data are available.

TABLE 12.—PROPOSED RMCL'S AND AADI'S FOR SOC'S PROPOSED FOR REGULATION

SOC	Safety factor	AADI [1] (mg/l)	Proposed RMCL (mg/l)
Acrylamide	100	[2] 0.007	0
Alachlor	NA	NA	0
Aldicarb, aldicarb sulfoxide and aldicarb sulfone	100	[2] 0.042	0.009
Carbofuran	100	0.18	0.036
Chlordane	100	0.03	0
cis-1,2-Dichloroethylene	1,000	0.35	0.07
DBCP	NA	NA	0
1,2-Dichloropropane	NA	NA	0.005
o-Dichlorobenzene	1,000	3.12	0.62
2,4-D	100	[2] 0.35	0.07
EDB	NA	NA	0
Epichlorohydrin	100	0.078	0
Ethylbenzene	1,000	[2] 3.4	0.68
Heptachlor	1,000	[2] 0.0025	0
Heptachlor epoxide	1,000	[2] 0.001	0
Lindane	1,000	[2] 0.01	0.0002
Methoxychlor	100	1.7	0.34
Monochlorobenzene	1,000	[2] 3.0	0.06
PCBs	NA	NA	0
Pentachlorophenol	100	1.1	0.22
Styrene	1,000	[2] 7.0	0.14
Toluene	100	10.1	2.0
2,4,5-TP	NA	0.26	0.052
Toxaphene	NA	NA	0
trans-1,2-Dichloroethylene	1,000	0.35	0.07
Xylene	1,000	[2] 2.2	0.44

[1] Does not consider carcinogenicity potential.
[2] These AADIs are termed "provisional" as they were determined from studies of less than lifetime duration (approximately 2 years for an animal study).
Note.—NA = Not available.

TABLE 13.— RISK ESTIMATES FOR SOC'S FOR WHICH DATA WERE AVAILABLE

SOC	Projected upper limit, excess lifetime cancer risk (10^{-6}), concentration in drinking water (µg/1)		EPA Classification	IARC Classification
	CAG	NAS		
Acrylamide	NA	NA	B[2]	Not classified.
Alachlor	[1] 0.15	NA	B[2]	Group 3.
Chlordane	0.02	0.028	B[2]	Group 3.
DBCP	0.025	NA	B[2]	Group 2B.
1,2-Dichloropropane	0.56	NA	C	Not classified.
Dioxin	[3] 2.2	NA	B[2]	Group 2B.
EDB	0.0005	0.11	B[2]	Group 2B.
Epichlorohydrin	3.54	NA	B[2]	Group 2B.
Heptachlor	0.0104	NA	B[2]	Group 3.
Heptachlor epoxide	0.00065	NA	B[2]	Not classified.
Hexachlorobenzene	0.02	0.54	B[2]	Group 2B.
Lindane	0.026	0.555	C	Group 3.
Monochlorobenzene	NA	2.35	C	Not classified.
PCBs	0.0079	0.16	B[2]	Group 2B.
Styrene	NA	NA	C	Group 3.
Toxaphene	0.03	NA	B[2]	Group 2B.

[1] Calculated by EPA's Office of Pesticide Programs.
[2] Times 10^{-1}.
Note.—NA = Not available.

TABLE 14.— SHORT-TERM ASSESSMENTS AND PROVISIONAL AADI'S FOR SOC'S FOR WHICH RMCLS ARE NOT PROPOSED

SOC	1 day (mg/l)		10-Day (mg/l)		Provisional AADI (mg/l)
	Child	Adult	Child	Adult	
Atrazine	NA	NA	NA	NA	[1] 0.75
m-dichlorobenzene	8.9	31.2	8.9	31.2	NA
Dioxin	[2] 1.0	[3] 3.5	[2] 1	[3] 3.5	[4] 3.5
Endrin	0.02	0.07	0.005	0.02	0.0016
Hexachlorobenzene	0.05	0.17	0.05	0.17	0.029

[1] Calculated by the NAS.
[2] Times 10^{-3} µg/l).
[3] Times 10^{-2} µg/l).
[4] Times 10^{-1}.
Note.—NA = Not available.

TABLE 15.—DRAFT SHORT-TERM ASSESSMENTS FOR SOCS FOR WHICH RMCLS ARE PROPOSED

SOC	1-day (mg/l)		10-day (mg/l)		Longer-term (mg/1)[1]	
	Child	Adult	Child	Adult	Child	Adult
Acrylamide	1.5	5.25	0.3	1.0	0.02	0.04
Alachlor	15	52.5	15	52.5	NA	NA
Aldicarb, aldicarb sulfoxide and aldicarb sulfone	0.012	0.042	0.012	0.042	0.012	0.042
Carbofuran	0.05	0.018	NA	NA	0.05	0.18
Chlordane	NA	NA	0.063	0.22	NA	NA
cis-1,2-Dichloroethylene	4.0	14	1.0	3.5	1.0	3.5
DBCP	0.2	0.7	0.05	0.17	NA	NA
1,2-Dichloropropane	NA	NA	0.09	0.31	NA	NA
o-Dichlorobenzene	NA	NA	NA	NA	8.9	31.2
2,4-D	1.1	3.85	0.3	1.1	NA	NA
EDB	NA	NA	0.008	0.027	NA	NA
Epichlorohydrin	NA	NA	0.14	0.5	0.022	0.076
Ethylbenzene	21	72	2.1	7.2	NA	NA
Heptachlor	NA	NA	0.01	0.035	NA	NA
Heptachlor epoxide	NA	NA	NA	NA	NA	NA
Lindane	NA	NA	1.2	4.3	0.033	0.12
Methoxychlor	6.4	22.4	2.0	7.0	NA	NA
Monochlorobenzene	NA	NA	1.8	6.3	9	30.5
PCBs	NA	NA	NA	NA	NA	NA
Pentachlorophenol	1.0	3.5	0.3	1.1	NA	NA
Styrene	27	94.5	20	70	20	70
Toluene	18	63	6	21	NA	NA
2,4,5-TP	NA	NA	0.2	0.75	NA	NA
Toxaphene	0.5	1.75	0.08	0.28	NA	NA
trans-1,2-Dichloroethylene	2.7	9.5	1.0	3.5	1.0	3.5
Xylene	12	42	NA	NA	7.8	27.3

Note:—NA = Not available. Adequate dose-response data were not available. Assessment derived for the next longer duration of exposure is considered to be protective in these cases.
[1] The longer-term number are not discussed in the section on the individual chemicals in the FR Notice but are discussed in the Health Advisory documents.

Table 16 lists the analytical methods presently available for the SOCs. There is no standardized EPA method for acrylamide. The analysis of acrylamide has been reported in the published literature using bromination of the double bond followed by gas chromatography analysis using an electron capture detector. Further research on this approach or an alternate procedure is required to develop a suitable analytical method for the determination of acrylamide in drinking water. Additional research is required on the development of multi-contaminant monitoring methods for the SOCs, including the use of capillary GC and capillary GC/MS techniques.

TABLE 16.—ANALYTICAL METHODS FOR SOCS

Compound	Method [3]
Acrylamide	No standardized EPA method.
Alachlor	Solvent extraction GC.
Aldicarb	HLPC; 531.
Atrazine	Solvent extraction GC; 619.
Carbofuran	Solvent extraction HPLC; 632.
Chlordane[1]	Solvent extraction GC; 608. Solvent extraction GC/MS; 625.
DBCP	Purge & Trap GC; 502.1. Purge & Trap GC/MS; 524.
cis- and trans-1,2-Dichloroethylene.	Purge & Trap GC; 502.1.
trans-1,2-Dichloroethylene	Purge & Trap GC; 524
o-Dichlorobenzene	Purge & Trap GC; 503.1. Purge & Trap GC/MS; 524.
m-Dichlorobenzene	Purge & Trap GC; 503.1. Purge & Trap GC/MS; 524.
1,2-Dichloropropane	Purge & Trap GC; 502.1. Purge & Trap GC; 601. Purge & Trap GC/MS; 624. Purge & Trap GC/MS; 524
2,4-D	Derivatization GC; 615.
EDB	Purge & Trap GC; 502.1.
Endrin	Solvent extraction GC; 608.
Epichlorohydrin	Direct Injection GC.
Ethylbenzene	Purge & Trap GC; 602.
Heptachlor	Solvent extraction GC; 608. Solvent extraction GC/MS; 625.
Hexachlorobenzene	Solvent extraction GC; 612.
Lindane	Solvent extraction GC; 608.
Methoxychlor	Solvent extraction GC; 608.
Monochlorobenzene	Purge & Trap GC; 503.1. Purge & Trap GC/MS; 524.
Pentachlorophenol	Solvent extraction GC; 604. Solvent extraction GC-MS; 625.
PCBs[2] PCB-1242	Solvent extraction GC; 608.
Simazine	Solvent extraction GC; 619.
Styrene	Purge & Trap GC; 503.1.
Toluene	Purge & Trap GC; 602.
Toxaphene[1]	Solvent extraction GC; 608.
2,4,5-TP	Derivatization GC; 615.
2,3,7,8-TCDD	Solvent extraction GC/MS; 613.
Xylenes: para-, meta-, ortho-.	Purge & Trap GC; 503.1.

[1] multiple peak response.
[2] PCBs included are 1260, 1254, 1248, 1242, 1232, 1221, and 1016.
[3] Series 600 methods are EPA methods for analysis of priority pollutants. Series 500 methods are EPA methods for analysis of drinking water contaminants.
NA—not available. FID—flame ionization detector. ECD—electron capture detector.

B. Proposed RMCLs

1. Acrylamide

Acrylamide (propenamide, CAS #79–06–1) is used primarily as a starting material for the manufacture of water soluble polymers employed to enhance oil and water recovery from wells, as flocculants in potable and waste water treatment, food processing, in paper making, dye application, adhesives, soil conditioners and permanent press fabrics. Acrylamide is extremely soluble in water (2.15×10^6 mg/l) and is soluble in alcohol, ether and acetone.

Analytical Methods. No EPA approved analytical method is presently available for acrylamide, although a research method is now available.

Human Exposure. Acrylamide monomer is a common contaminant of polyacrylamide used in food production and as a coagulant aid in the water treatment process. Polyacrylamide may be contaminated with up to 0.05 percent acrylamide monomer, which upon leaching, could yield a 0.5 μg/day intake by humans from drinking water alone. Technical grades of polyacrylamide, having higher levels of acrylamide monomer, are used in drilling new potable water wells. These acrylamide residues may remain in the surrounding soils. Technical grades of polyacrylamide are used in mine management and reclamation and have been reported to have contaminated local water supplies with acrylamide monomer. No monitoring data are available to describe the frequency or level of human exposure via food, air or drinking water. While monitoring for acrylamide has been limited, the potential for occurrence in drinking water exists because of its use as an additive in drinking water treatment processes.

Health Effects. The principal toxic effect from exposure to acrylamide (monomer) over any duration of time and by any route in animals is peripheral neuropathy. Subchronic studies have demonstrated a variety of effects, including atrophy of skeletal muscles in the hind quarters, testicular atrophy and weakness in the limbs. Long-term exposure to acrylamide also has been shown to result in neurotoxic effects and weakness in the hind quarters. Case reports suggest that similar effects occur in the human following exposure via the dermal, oral or inhalation routes. Recent evidence shows that acrylamide in carcinogenic in mice and rats when administered by one of several routes: oral, topical or intraperitoneal.

No adequate dose-response data representing the oral route of exposure are available from which to develop short-term assessments. However, in the light of substantial chemical disposition evidence showing that acrylamide is absorbed rapidly and completely by virtually any route of exposure, it is considered acceptable to use data generated following exposure via these other routes. The 1-day assessments were derived from a NOAEL of 15 mg/kg identified in an animal study (Miller, et al. 1983. Altered Retrograde Axonal Transport of Nerve Growth Factor After Single and Repeated Doses of Acrylamide. Toxicol. Appl. Pharmacol. 69:96–101). While measuring the rate of retrograde axonal transport of iodinated nerve growth factor in rats treated with single intraperitoneal doses, the authors showed that significant inhibition of transport ensued at or above doses of 25 mg/kg, while no significant changes were seen at or below 15 mg/kg. The 1-day assessments were derived by applying an uncertainty factor of 100 to the NOAEL of 15 mg/kg, yielding a value for the 10 kg child of 1.5 mg/l which assumes consumption of 1 liter of water per day and a value for the 70 kg adult of 5.25 mg/l which assumes consumption of 2 liters of water per day.

The 10-day assessments were derived from a NOAEL identified in a drinking water study (Gorzinski, et al. 1979. Results of Palatability (12-day) and Tolerance (21-day) Studies on Acrylamide Monomer Administered in the Drinking Water of Rats. Dow Chemical Company. Unpublished report). The monomer was administered in drinking water at levels of 0, 1, 3, 10 or 30 mg/kg bw/day for 21 consecutive days. Based upon histological examination of peripheral nerves at both the light and electron microscopic levels, it was determined that effects occurred at the two higher doses, while no significant changes were apparent at the two lower doses. A NOAEL of 3 mg/kg/day thus was identified. The 10-day values were derived by applying an uncertainty factor of 100 to the NOAEL, yielding a level of 0.3 mg/l for the 10 kg child which assumed consumption of 1 liter of water per day and a level of 1.05 mg/l for the 70 kg adult which assumes consumption of 2 liters of water per day.

The study selected for the derivation of a provisional AADI was a subchronic study in which rats were administered daily doses of 0, 0.05, 0.2, 1, 5 or 20 mg/kg in their drinking water (Burch, et al. 1980. J. Environ. Path Tox. 4:157–182). The parameters measured were gross neuropathy as observed by the limb splaying method, ultrastructural examination of peripheral motor nerves, hematology, clinical chemistry and body and organ weights. On the basis of the most sensitive measure of toxicity, the unltrastructural examination, it was concluded that 0.2 mg/kg was the NOAEL. Using this NOAEL, an uncertainty factor of 100 based upon an animal study with the NOAEL identified, an uncertainty factor of 10 to convert from subchronic to chronic exposure and consumption of 2 liters of water per day, a provisional AADI of 0.007 mg/l was determined.

Acrylamide did not elicit mutagenic activity in the Ames test (both with and without microsomal activation) or in the hepatocyte culture DNA repair assay (Bull, et al. 1984. Carcinogenic Effects of Acrylamide in Sencar and A/J mice. Cancer Res. 44:107–111; Miller, et al. 1984. Lack of Genotoxicity of Acrylamide Using the Hepatocyte Primary Culture (HPC)/DNA Repair Test. Abstract No. 138. Presented at the 1984 meeting of the Society of Toxicology, Atlanta, GA. The Toxicologist 4(1):35). Chromosome aberrations were noted in the spermatogonia of mice exposed to 75 mg/kg/day in the diet for 2–3 weeks, but bone marrow cells were not affected (Shiraishi, Y. 1978. Chromosome Aberrations Induced by Monomeric Acrylamide in Bone Marrow and Germ Cells of Mice. Mut. Res. 57:313–324). Both the marrow cells and spermatogonia showed a striking decrease in mitotic index following a single intraperitoneal dose of 50 to 150 mg/kg.

Only one published study (Bull, et al. 1984. Carcinogenic Effect of Acrylamide in Sencar and Strain A/J Mice. Cancer Research. 44:107–111) is available which addresses the carcinogenic effects of acrylamide. This study showed that acrylamide acted as a tumor initiator in the skin of the female Sencar mouse when administered orally, topically or by intraperitoneal injection. Acrylamide also increased the yield of lung adenomas in strain A/J mice when given orally. In addition, preliminary data from another study show that acrylamide causes a significant increase in tumor incidences at several sites in both male and female rats exposed to acrylamide in their drinking water. A quantitative risk assessment has not been performed on acrylamide, pending submission of the data to the Agency for review. Acrylamide has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment based upon the positive results in studies in mice and rats.

The data strongly suggest that acrylamide monomer is carcinogenic in animal species. Because of these potential adverse health effects and the fact that acrylamide is likely to be occurring in water supplies, due to its use as an additive in the drinking water treatment process, EPA is proposing to regulate this contaminant. The RMCL will be based upon carcinogenic effects and an RMCL of zero is proposed.

2. Alachlor

Alachlor [(2-chloro-2',6' diethyl-n-(methoxymethyl) acetanilide); CAS # 15972-60-8] is a herbicide used primarily

on corn and soybeans. Alachlor is slightly soluble in water and can enter water systems by runoff from agricultural fields into surface water or by leaching downward through soil to ground water.

Analytical Methods. Analytical methods available for analyzing alachlor in drinking water include the solvent extraction-gas chromatography technique.

Human Exposure. Alachlor is registered primarily for use on beans, corn, cotton, peanuts, peas, sorghum, soybeans, sunflowers and woody ornamentals. Tolerances for alachlor have been established for eggs, milk, and the fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep.

Estimates of dietary exposure to alachlor have been calculated based upon the estimated level of each food item for which a tolerance has been set in the typical diet. These calculations suggest a total dietary exposure of 4×10^{-4} mg/kg/day.

There are no data to indicate the presence or absence of alachlor in ambient air at production and use sites, or in urban air.

Five regional studies conducted in the midwestern United States provide evidence of the occurrence of alachlor in surface and ground water. During the spring and summer of 1981, one study showed alachlor to be present in 80 percent of the samples (293) taken from 12 different streams. The maximum concentration observed was 104 μg/l. During 1982–1984, alachlor was also shown to be present in surface water sources, at a maximum concentration of 75 μg/l.

In 1980, 2 out of 14 wells sampled in Nebraska were found to contain alachlor levels of approximately 0.04 μg/l. Recent results from drinking water wells in Iowa (1982–1984) showed levels of alachlor up to 16 μg/l, with levels typically less than 3 λg/l. Drinking water samples of tap water from Ohio have also detected alachlor at similar levels. In Maryland, 4 out of 30 wells found to contain alachlor at levels approximately 0.4 μg/l.

Other drinking water supplies have been found to have detectable levels of alachlor. Selected surface water supplies in one State have been reported to contain as much as 14.3 μg/l alachlor during spring and summer months. In some instances the drinking water level differed little from the level found in raw water. Alachlor was detected in 4 out of 104 samples from NSP for organics. Levels ranged from 0.1–0. 9 μg/l.

Health Effects. Alachlor exhibits relatively low acute toxicity by the oral (rat $LD_{50}=0.93$ g/kg), dermal (rabbit $LD_{50}=13.3$ g/kg), or inhalation (rabbit $LC_{50}>5.1$ ml/l) routes of exposure (Monsanto. 1978a. Acute Oral Rat, Acute Dermal Rabbit. Unpublished study received 1978; CDL:241273; Monsanto. 1981c. Acute Inhalation LD_{50} Rat. Unpublished study received 1981; CDL:248053). Although alachlor is a skin sensitizer and causes ocular lesions upon chronic exposure, the technical product has only slight skin and eye irritation potential after an acute exposure (Monsanto. 1978b. Primary Eye and Primary Dermal Irritation Rabbit. Unpublished study received 1978; CDL:241273; Monsanto. 1984a. Dermal Sensitization Guinea Pig. Unpublished study received 1984; CDL:252772).

A two year rat feeding study in the Long-Evans strain of rat showed alachlor to be toxic at all doses tested; 14.0, 42.0 and 126.0 mg/kg/day (Monsanto. 1982. Environmental Fate of Microencapsulated Alachlor: Vol. I and II. Unpublished study received 1982. CDL:070841). The principal toxic effects of concern were heptatotoxicity and an ocular lesion, referred to as the uveal degeneration syndrome (UDS). UDS is characterized in its mildest form by free floating irideal and chorodial pigment in the ocular chamber and pigment deposition on the cornea and lens. In its most severe form, the syndrome is characterized by bilateral degeneration of the iris and diminution of the size of the ocular globe with secondary total cataract formation.

A follow-up two-year feeding study in the same strain of rat was conducted at 0.5, 2.5 and 15.0 mg/kg/day (Stout. 1983. A Chronic Study of Alachlor Administered in Feed to Long-Evans Rats. Unpublished study received 1984. CDL:252498). There was a small increase at the high dose in animals exhibiting the initial stage of UDS, specifically molting of retinal pigmentation.

No duration specific data are available to derive a one-day health advisory; therefore, it is recommended that the ten-day health advisory be applied for the one-day assessment.

The ten-day assessment is derived from a teratogenicity study in the rat reported by Rodwell and Tracher. 1980 (Teratology study in rats. IRDC No. 401–058; IR–79–020. Unpublished study including submitter study, received Oct. 16, 1980, under EPA Reg. No. 524–385, prepared by International Research and Development Corporation, submitted by Monsanto Agricultural Products Co., St. Louis, MO. CDL: 252570). No teratogenic effects were observed at 400 mg/kg/day; however, this level did produce maternal and fetotoxicity. A maternal and fetotoxic NOAEL was established at 150 mg/kg/day when alachlor was administered to rats on day 6 through 15 of gestation. Using the NOAEL of 150 mg/kg/day, a 10 day health advisory for a 10 kg child is 15 mg/l and for a 70 kg adult is 52.5 mg/l.

Alachlor feeding studies have demonstrated oncogenic effects which include lung tumors in mice, and stomach, thyroid, and nasal turbinate tumors in rats. Two chronic feeding studies were conducted in the Long Evans strain of rat with alachlor. In the first study, the technical material was stabilized with epichlorohydrin during the first year of the study (Daly. 1981b. An Eighteen-Month Chronic Feeding Study of Alachlor in Mice. Unpublished study received 1981, CDL:07168–A, 070169) and fed to 50 animals/sex at dose levels of 14, 42, and 126 mg/kg/day. During the second year of this study, alachlor stabilized with epoxidized soybean oil was the test material throughout the study.

Dose-related responses were observed for tumors of the nasal turbinate of both sexes for the mid and high doses. Also, increases were observed in the incidence of malignant stomach tumors (described by the authors as neoplasms pluripotent in ability to form a mixed carcinomasarcoma-type tumor) in the high dose of both sexes ($p<0.001$). In addition, thyroid follicular tumors (adenomas plus carcinomas) appeared to increase in both sexes at the high-dosage level with the increase being significant ($p<0.001$) in males. The incidence of the nasal turbinate, stomach and thyroid tumors as well as other tumors, i.e., liver and brain, are considered of potential biological significance.

In the second two-year feeding study (Stout. 1983a. A Chronic Study of Alachlor Administered in Feed to Long-Evans Rats. Unpublished study received 1984. CDL:252498–7), throughout which epoxidized soybean oil (1.28%) was used as a stabilizer in the test material, three treatment groups of 50 males and 50 female Long-Evans rats received 0.5, 2.5, and 15 mg/kg/day. Data from an additional study run concurrently with the previously discussed study have recently been submitted to EPA (Stout. 1983. A Chronic Study of Alachlor Administered in Feed to Long-Evans Rats. Unpublished study received 1984. CDL:252498). This additional study used a fourth treatment group, 126 mg/kg/day, that was exposed to the new technical material (without epichlorohydrin as a stabilizer). A group was treated for five to five and one-half months and then put on a control diet

for the remainder of the two year period. This study indicates that the tumor response observed in the earlier study cannot be explained by the presence of epichlorohydrin in the test material and suggests that partial lifetime exposure (approximately one-fourth of the lifespan of the animals) resulted in a similar tumor incidence as a lifetime exposure.

The IARC have classified alachlor in Group 3; inadequate evidence for carcinogenicity in humans and inadequate evidence for carcinogenicity in animals. This classification was carried out before the results of the alachlor feeding studies were available. Alachlor has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Risk Assessment, based upon positive results in feeding studies in mice and rats.

EPA's Office of Pesticide Programs has derived estimates of risk of daily exposure to alachlor in drinking water based upon the incidence of tumors of the nasal epithelium, stomach and thyroid from an ingestion study in rats. The estimated lifetime cancer risk rates are shown in Table 13.

The available data indicate that alachlor has carcinogenic effects in animals. Alachlor has been detected in public water systems and is highly mobile in the environment. Thus, EPA is proposing to regulate this contaminant and an RMCL will be based upon carcinogenicity; an RMCL of zero is proposed.

3. Aldicarb, Aldicarb Sulfoxide and Aldicarb Sulfone

Aldicarb [2-methyl-2-(methylthio)propanal-o-[(methylamino) carbonyl]oxime; CAS #116-06-3] also known as Temik, is a registered pesticide used to control insects, mites and nematodes. Aldicarb's high aqueous solubility is one reason that water serves as a pathway for its movement in the environment. Aldicarb is not tightly bound to either organic material or clays. Although the vapor pressure of aldicarb is low, aldicarb may enter air directly during and following application, spillage, or disposal. EPA estimated that 3.5 million pounds of aldicarb were used in 1979. Commercial agricultural applications account for 90 percent of the estimated annual domestic usage. Aldicarb also is used on ornamentals (commercial field grown and nursery plantings, greenhouse crops, and potted plants).

Analytical Methods. Analytical methods available for analyzing aldicarb and its degradation products in drinking water include the high pressure liquid chromatography technique.

Human Exposure. The data obtained on levels of aldicarb in food in the U.S. were insufficient for use in estimating typical dietary intake of aldicarb. However, a worst-case estimate of dietary intake from food residues on raw agricultural commodities could approach 106 μg/day for a 70 kg adult (1.5 μg/kg/day).

Residues are approved for specific crops. In a 1982 study of citrus fruit, no detectable aldicarb residues were found in any samples of oranges. One grapefruit sample contained 50 μg/kg aldicarb. Aldicarb residues, ranging from a trace to 470 μg/kg, were identified in 78 percent of samples of potatoes analyzed in 1979. Ninety-four percent of samples analyzed in 1980 contained detectable residues ranging from 50–520 μg/kg.

No data were available on levels of aldicarb in ambient air.

Aldicarb has been detected in ground water used as drinking water. Of the 8404 samples collected from wells on Long Island, New York, as of 1981, 29 percent contained total aldicarb residues greater than the detection limit of 1 μg/l. Wells near a farm in northern California showed aldicarb residues of up to 24 μg/l. Three out of nine wells sampled in southern New Jersey contained aldicarb concentrations of 3, 4, and 50 μg/l; a water sample collected near citrus groves in Florida was reported to contain 3.5 μg/l aldicarb. Data on water samples from wells in Wisconsin, Florida, Maine, Virginia and North Carolina indicated that samples from approximately 4 percent of the wells studied had aldicarb concentrations in excess of 10 μg/l. Aldicarb residues also have been found in ground water in New Jersey, Rhode Island (recent USGS study), Missouri and Massachusetts. Aldicarb also has been detected in surface waters.

Health Effects. Animal studies have demonstrated that aldicarb, as well as its sulfoxide and sulfone metabolites, are absorbed readily by mammalian and non-mammalian species. The parent compound and its sulfoxide metabolites are potent cholinesterase inhibitors; the sulfone is substantially less so at equivalent doses. Laboratory studies have found that aldicarb is excreted rapidly from the body, primarily via the urine.

The principal toxic effect of aldicarb and its sulfoxide and sulfone metabolites is cholinesterase inhibition as measured in plasma, erythrocyte and brain. This inhibition has been demonstrated to be transient in nature, when not fatal, due to the spontaneous recovery of the inhibited enzyme.

Given the nature of the primary toxicity of aldicarb and its metabolites (rapidly-reversible cholinesterase inhibition), the same NOAEL can be used as the basis for the derivation of allowable levels over virtually any duration of exposure. This NOAEL (0.125 mg/kg/day) was identified in a study in which rats were administered doses of aldicarb sulfoxide at levels of 0, 0.125, 0.25, 0.5 or 1.0 mg/kg bw or aldicarb sulfone at levels of 0, 0.2, 0.6, 1.8, 5.4 or 16.2 mg/kg bw in the diet for periods of 3 or 6 months (C.S. Weil and C.P. Carpenter, 1968a,b. Temik sulfoxide. Temik sulfone. Results of Feeding in the Diet of Rats for Six Months and Dogs for Three Months. Mellon Institute Report 31–141 and 31–142. EPA Pesticide Petition No. 9F0798). The results of the study demonstrated a substantial reduction of cholinesterase activity at the three highest dosage levels of both compounds when measured immediately after cessation of feeding. A NOAEL of 0.125 mg/kg bw was determined for the more toxic sulfoxide.

From the NOAEL of 0.125 mg/kg/day, a provisional AADI of 0.042 mg/l for the 70 kg adult can be derived by applying an uncertainty factor of 100, appropriate for use with a NOAEL derived from animal data, and assuming consumption of 2 liters of water per day. The provisional AADI (0.042 mg/l) is also appropriate for use as 1-day and 10-day assessments for the 70 kg adult. The 1-day and 10-day assessment for the child (assuming a 10 kg child consuming 1 liter of water per day) is 0.012 mg/l based upon the same study.

Conclusive evidence on the mutagenicity of aldicarb is not currently available, although the few studies done to date do not suggest mutagenic potential. Aldicarb has not been shown to be carcinogenic in animals. The National Cancer Institute (NCI) conducted a bioassay in which rats and mice were fed 2 or 6 ppm aldicarb in the diet for 103 weeks (0.1 or 0.3 mg/kg, bw, respectively) (NCI. 1979. Bioassay of Aldicarb for Possible Carcinogenicity. NCI–CG–TR–13h U.S. HEW PHS, National Institutes of Health). The conclusions of this study were that no tumors could be attributed solely to aldicarb administration. Two 2-year feeding studies in rats also reported that aldicarb did not produce a statistically significant increase in tumors when compared to controls (C.S. Weil and C.P. Carpenter. 1965. Two-year Feeding Study of Compound 21149 in the Diet of Rats. Unpublished report; C.S. Weil, 1972. Aldicarb (A), Aldicarb Sulfoxide (AsO), Aldicarb Sulfone (AsO_2) and a

1:1 Mixture of ASO:ASO_2. Two year Feeding in the Diet of Rats. Unpublished report). Aldicarb has been classified in EPA's Group E, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon negative results in several animal studies.

The Food and Agricultural Organization/World Health Organization has proposed ADIs for aldicarb residues of 0–0.001 mg/kg/day in 1979 and 0–0.005 mg/kg/day in 1982. The NAS (1977; 1983) proposed an ADI of 0.001 mg/kg/day based upon two-year feeding studies in rats and dogs and a suggested-no-adverse-response-level (SNARL) of 7 μg/l using the same studies with an uncertainty factor of 1000. The SNARL is protective for a 70 kg adult for whom drinking water contributes 20 percent of the daily exposure to aldicarb residues. EPA's Office of Pesticide Programs has established an ADI of 0.003 mg/kg/day (46 FR 57047) based upon the same study used to derive the provisional AADI.

Ordinarily, an RMCL is proposed for the parent compound. In this case, however, the RMCL is proposed for total aldicarb residues (the parent compound as well as the sulfoxide and sulfone degradation products). The reason for this is that the residues of aldicarb found most often in water samples are the sulfoxide and sulfone, with relatively little of the parent compound being present. In addition, the analytical methodology most commonly used to determine aldicarb residues in water samples includes oxidation of the residues to the sulfone, followed by identification/quantification of the residues as sulfone. Toxicologically, the RMCL is based upon data from studies on the sulfoxide. This is because the sulfoxide is slightly more potent that the parent compound and significantly more potent than the sulfone as an inhibitor of cholinesterase, the end-point of toxicity considered to be the most sensitive measure of an effect.

EPA is proposing to regulate this contaminant based on its toxicology, occurrence in water and potential occurrence in drinking water supplies. The RMCL for aldicarb residues is based upon the effect of cholinesterase inhibition. The proposed RMCL of 0.009 mg/l is considered protective of the 70 kg adult for whom there is assumed a 20 percent contribution to exposure from drinking water. This RMCL is also considered to be protective of the 10 kg child over durations of exposure of less-than-lifetime and for whom drinking water constitutes a greater contribution to total exposure.

Questions for Comment:

1. Is it appropriate to propose an RMCL for aldicarb residues to be protective of the 70 kg adult, rather than the 10 kg child? The most sensitive end-point of toxicity (cholinesterase inhibition) is an acute, rapidly-reversible phenomenon which is the basis for the derivation of allowable exposure levels over all durations of exposure.

2. In the allocation of an RMCL for aldicarb residues, it was assumed that drinking water could contribute 20 percent of an individual's daily exposure to these residues. Is this appropriate, in light of the potential for significant exposure via non-water sources for the 70 kg adult, but more limited potential for the 10 kg child?

4. Carbofuran

Carbofuran (2,3-dihydro-2,2-dimethyl-7-benzofuranol-methylcarbamate; CAS # 1563–66–2) is an insecticide and nematocide. EPA estimated that about 11 million pounds were used in the U.S. during 1980. Eighty-four percent of the carbofuran is used on corn. Technical carbofuran has an aqueous solubility of 700 mg/l and is mobile in water.

Analytical Methods. Analytical methods available for analyzing carbofuran in drinking water include the solvent extraction-gas chromatography/mass spectrometry and the solvent extraction-high pressure liquid chromatography techniques.

Human Exposure. Data obtained on levels of carbofuran in foods were insufficient for use in estimating typical dietary intake levels. However, carbofuran residues are permitted on several crops. Peanuts from Arkansas have been reported to contain up to 25 μg/kg carbofuran. If all crops contained the maximum residues permitted, the daily intake for adults would be approximately 530 μg/day.

No data were available on levels of carbofuran in ambient air.

Carbofuran has been found in ground water samples from New York and Wisconsin at levels of 1–50 μg/1. It also has been detected in ground water in three other States.

Health Effects. Like other members of the class of carbamate pesticides, carbofuran is a potent inhibitor of cholinesterase. It is expected to be absorbed readily and rapidly by all likely routes of human exposure: oral, dermal and inhalation. Carbofuran's oxidative metabolites, 3-hydroxycarbofuran and 3-ketocarbofuran, also presses significant cholinesterase inhibitory properties. On the other hand, the hydrolytic metabolites, 3-keto-7-phenol and 7-hydroxycarbofuran phenol do not. Excretion of carbofuran metabolites is relatively rapid and the compound(s) would not be expected to accumulate significantly in mammalian tissues following repeated exposures.

The principal adverse health effect occurring following exposure to carbofuran is the rapid inhibition of cholinesterase activity. The effect has been demonstrated to be transient in nature, when not fatal, due to the spontaneous recovery of the inhibited enzyme at sites in the central and peripheral nervous systems. Other acute effects on the immune system and blood parameters have been reported. These, too, appear to be reversible once exposure is terminated. In addition, at doses above those at which inhibition of cholinesterase is noted, aspermia and testicular degeneration in dogs and some minimal decreases in rat pup survival also have been observed.

A study by FMC Corporation (1977. Industrial Hygiene Studies, final report. MRI Project No. 4230–B. EPA Accession No. 241303) was selected as the basis for the calculation of 1-day assessments for the 10 kg child and the 70 kg adult. Adult male human volunteers were administered a single oral dose of carbofuran shortly after eating breakfast. Of the three doses employed (0.05, 0.10 or 0.25 mg/kg bw), only the lowest dose was without effect, as identified by a lack of a statistically and biologically significant depression of red blood cell cholinesterase activity levels. To the NOAEL of 0.05 mg/kg, an uncertainty factor of 10 was applied, consistent with accommodation for intraspecies variability. This resulted in a 1-day assessment for the 10 kg child of 0.05 mg/l and for the 70 kg adult, 0.18 mg/l. No adequate dose-response data exist from which the 10-day assessment could be derived. Since, however, the end-point of toxicity that is of concern in this case is a rapidly-reversible, transient effect, the 1-day assessments for the 10 kg child and the 70 kg adult also can serve as the 10-day assessment for each individual.

The one-year dietary study in beagle dogs was selected to serve as the basis for the derivation of the AADI (FMC Corporation, Agricultural Chemical Group. 1983. One-year Chronic Oral Study in Beagle Dogs with Carbofuran. Study No. FMC A81–605/Toxigenics 410–0715. EPA Accession No. 250740–250744). Groups of animals were administered daily doses of 0, 10, 20 or 500 ppm carbofuran in the feed. These dietary levels corresponded to approximate daily doses of 0, 0.25, 0.5 or 12.5 mg/kg bw/day. From the results of this study, it was determined that the middle dose (0.50 mg/kg/day) was the

NOAEL, based upon the absence of a biologically significant depression of cholinesterase activity or reproductive effect in the males. Applying an uncertainty factor of 100 to the NOAEL of 0.50 mg/kg/day and assuming consumption of 2 liters of water pey day, an ADI of 0.005 mg/kg/day and an AADI of 0.18 mg/l was calculated for the 70 kg adult. This AADI is supported further by evidence from the 2-year rat feeding study (FMC Corporation, Agricultural Chemical Group. 1980. Two-year Dietary and Carcinogenicity Study in Rats. Carbofuran Technical Report No. Act. 130.51. EPA Assession No. 244491). In this study, groups of rats were fed 0, 10, 20 or 100 mg carbofuran/kg diet for 2 years. A NOAEL Of 1 mg/kg/day (the middle treatment dose) was identified, to which an uncertainty factor of 200 was applied to protect against cholinesterase depression and systemic effects. Again assuming consumption of 2 liters of water per day, and AADI of 0.18 mg/1 was calculated for the 70 kg adult. Both of these studies which were used to determine the provisional AADIs are long-term studies (1-year and 2-years) with many dose levels. These studies are more appropriate for determining a lifetime number than the human data (used to determine the short-term assessment) which consisted of one dose applied in a single exposure.

The mutagenic potential of carbofuran has been tested in a number of short-term assays. The majority of the results presented no evidence of mutagenicity. Two studies yielded equivocal results. The carcinogenic potential of carbofuran was evaluated in lifetime dietary studies in the rat and the mouse (FMC Corporation, Agricultural Chemical Group. 1980. Two-year Dietary Toxicity and Carcinogenicity Study in Rats. Carbofuran Technical Report No. ACT 130.51. EPA Accession No. 244491; Ibid. 1980. Two-year Dietary Toxicity and Carcinogenicity Study in Mice. Carbofuran Technical Report No. ACT 150.52. EPA Accession No. 244489). In neither study were there statistically increased tumor incidences attributable to exposure to the compound. Carbofuran has been classified in EPA's Group E, according to EPA's Proposed Guidelines for Risk Assessment, based upon the negative results in studies in rats and mice.

EPA is proposing to regulate carbofuran because of its potential adverse effects on health and potential for occurrence in drinking water. Exposure to carbofuran at sufficient levels results in a rapidly-reversible inhibition of cholinesterase activity, as well as possible reproductive and immune effects. An RMCL of 0.036 mg/l is based upon the AADI of 0.18 mg/l and an assumed drinking water contribution of 20 percent.

5. Chlordane

Chlordane (1,2,4,5,6,7,8,8-octachloro-2,3,3a,4,7,7a-hexahydro-4,7methano-1H-indene; CAS # 57-74-9) is a broad spectrum insecticide. Technical chlordane is a mixture of stereo-isomers and other chlorinated analogs, including heptachlor. The water solubility of chlordane is 150-220 μg/l at 22 °C. Chlordane is relatively non-volatile with a vapor pressure of $1x10^{-5}$ mm Hg at 25 °C.

Chlordane is currently the most extensively used insecticide for subterranean termite control in the United States. Prior to the 1977 cancellation of registrations for agricultural and home garden use, chlordane was used for the control of soil insects and ants.

Analytical Methods. Analytical methods available for analyzing chlordane in drinking water include the solvent extraction chromatography and solvent extraction-gas chromatography/mass spectrometry techniques.

Human Exposure. In the FDA FY 77 compliance program report on pesticides and metals, chlordane was detected in 2.6 percent of foods sampled. Chlordane occurred in 1.8 percent of raw agricultural product samples, 9.3 percent of fish and marine animal samples, 0.2 percent of processed food samples, 1.4 percent of processed animal feed samples, and 2.5 percent of egg and egg product samples. In the FDA FY 79 total dietary study for adults, no chlordane was detected in any of the samples.

The USDA reported chlordane residues in violation of maximum allowable levels (300 ug/kg on raw agricultural commodities) in 0.1 percent of fat samples of various animal species intended for human consumption during the years 1982-1983.

Chlordane has been detected in ambient air at levels as high as 204 ng/m^3. In the Surburban Air Sampling Program in 1975, 15 samples were collected at three suburban locations. Nine samples were positive for chlordane with a maximum value of 59 ng/m^3.

Chlordane has occasionally been reported in wells near areas treated for termite control. In addition, chlordane was detected at low levels in the New Orleans Water Supply Study conducted by EPA. Five wells in New Jersey contained chlordane above 0.01 μg/l (range 0.01-0.02 μg/l). Chlordane has been detected in drinking water in a total of five States. One state found that 49 percent of the systems analyzed (87 ground systems) were positive. In the 1975 Region V Survey, one sample contained gamma-chlordane at a level of 0.004 μg/l (detection limit not reported).

Contamination of public water systems has been reported in several cases which occurred from back syphonage from tank filling operations during pesticide applications.

Chlordane has been identified at three hazardous waste sites designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of chlordane ranged from unknown amounts migrating in water, 782-2300 mg/l in sediments, to 101 mg/l in soil.

Health Effects. The principal non-carcinogenic effects of chlordane from both acute and chronic exposure include neurotoxicity, induction of hepatic microsomal enzyme activity and liver effects.

Sufficient dose response data were not available to derive 1-day assessments. However, it should be noted that the ten-day assessment would also be protective for the one-day exposure. Ten-day assessments were based upon a study in which rats were given by gastric intubation doses of 0, 6.25, 12.5, 25.0, 50.0, 100.0 or 200 mg/kg chlordane for 15 days (Ambrose, et al. 1953. Toxicological and Pharmacological Studies on Chlordane. Arch. Ind. Hyg. Occup. Med. 7:197). The minimal histopathological changes such as presence of abnormal intracytoplasmic bodies of various diameters were evident at a dose level of 6.25 mg/kg. Using 6.25 mg/kg as the LOAEL, an uncertainty factor of 100 based upon an animal study and consumption of 1 liter (child) or 2 liters of water (adult) per day, 10-day assessments of 0.063 mg/l for a 10 kg child and 0.22 mg/l for a 70 kg adult were calculated.

An AADI for chlordane was derived based upon a two-year feeding study in dogs where 0.075 mg/kg/day (3 mg/kg in diet) was identified as the NOAEL (Vettorazzi, 1975. Toxicological Decisions and Recommendations Resulting from the Safety Assessment of Pesticide Residues in Food. Crt. Rev. Toxicol. 4:125). Using 0.075 mg/kg/day as the NOAEL, an uncertainty factor of 100 based upon an animal study and consumption of 2 liters of water per day, an AADI of 0.03 mg/l was calculated.

Chlordane was shown to be mutagenic in studies with transformed human cells in culture. A National

Cancer Institute study (NCI. 1977a. Bioassay of Chlordane for Possible Carcinogenicity. NCI Carcinogenesis. Tech. Rep. Ser. No. 9) examined the carcinogenic effects of chlordane. Male and female mice were fed diets containing analytical-grade chlordane for 80 weeks, with the results showing a highly significant dose-dependent incidence of hepatocellular cacinoma in both male and female mice. Hepatic nodules and liver hyperplasia were also produced in rats. A study examining the reproductive effects of chlordane concluded that chlordane in the diet [16 mg/kg) of male and female rats from weaning appears to interfere with fertility and survival of the litters (Ambrose, et al. 1953a. Toxicological and Pharmacological Studies on Chlordane. Arch. Ind. Hyg. Occup. Med. 7:197). The IARC classified chlordane in Group 3; inadequate evidence for carcinogenicity in humans, limited evidence for carcinogenicity in animals and inadequate evidence for activity in short-term tests. Chlordane has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon studies showing positive results in mice and female rats.

EPA's CAG and the NAS have calculated risk estimates (see Table 13) based upon the NCI study.

The WHO recommended guideline value (1984) is 3 µg/l for chlordane. This was based upon an acceptable daily intake of 0.001 mg/kg/day, with the assumption that not more than one percent of the ADI would be derived from drinking water.

A detection and odor threshold value of 0.005 mg/l has been reported in the literature for chlordane.

The available data indicate that chlordane has carinogenic effects in animals. For this reason and because of the occurrence of this contaminant in a number of drinking water supplies, EPA is proposing a primary regulation for chlordane. The RMCL will be based upon carcinogenic effects and an RMCL of zero is proposed.

6. Dibromochloropropane

Dibromochloropropane (1,2-dibromo-3-chloropropane (DBCP); CAS #96-12-8) is a soil fumigant used for nematode control on crops. DBCP is moderately soluble in water (approximately 1 g/l). Recent information suggests that DBCP may readily leach into aquifers used for drinking water.

Util 1977, DBCP was used in commercial agricultural applications. It was also used for non-crop applications, including commercial turf. Presently all uses have been cancelled.

Analytical Methods. Analytical methods available for analyzing DBCP in drinking water include the purge and trap-gas chromatography and the purge and trap-chromatography/mass spectrometry techniques.

Human Exposure. DBCP residues have been detected in U.S foods. In 1978, the FDA detected residues in carrots grown in soil fumigated with DBCP. Levels ranged from 20–1,500 µg/kg. Residues were detected in broccoli, cabbage, cauliflower and cucumbers in the range of 10–1,120 µg/kg. Additionally, residues were detected in peanut kernels in the range of 10–40 µg/kg.

The FDA compliance program report for FY 79 reported residues of DBCP in samples of domestic and imported fish. Seven (0.5%) out of 1,515 fish samples contained DBCP in excess of the detection limit.

DBCP has been detected in ambient air. One composite study of volatile organic chemicals in the atmosphere from locations nationwide showed the pressure of DBCP in ambient air samples in one location. A mean concentration of 6.4 ng/m^3 in seven air samples was calculated for DBCP (median, 1.8 ng/m^3).

Several regional studies have documented the presence of DBCP in ground water. Positive samples have been detected in Hawaii, California, Arizona, South Carolina and Maryland, with concentrations typically ranging from 0.02–20 µg/l. One of these States found 62 out of 92 samples to be positive, in ground water. DBCP is reported to be mobile in runoff and through soils.

DBCP has been identified at one hazardous waste site designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of DBCP ranged from 0.08 mg/l in drinking water, 95 mg/l in ground water, to 2600 mg/l in soil. DBCP was also detected in ground water at a hazardous waste site in Colorado and a site in California.

Health Effects. DBCP is absorbed by the gastrointestinal tract, the lungs and the skin and is widely distributed throughout the body. Effects of acute, oral exposure to DBCP in rats include impaired renal function, hepatocelluar necrosis, loss of spermatogenic elements in the testes and testicular and epididymal atrophy. Similar effects have been observed for subchronic oral exposure, while chronic exposure in animals has resulted in high incidences of toxic tubular nephropathy.

Antifertility effects in men have been associated with exposure to DBCP.

One-day assessments were calculated based on a study in rates (Kluwe, W.M. 1985. Initial and Residual Toxicity following Acute Exposure of Developing Male Rats to Dibromochloropropane. Toxicol. Appl. Paramacol. 79:54–68) where single day, subcutaneous doses of DBCP induced renal lesions in 6-day-old rats. Using a 20 mg/kg/day LOAEL, an uncertainty factor of 1000, and consumption of 1 liter (child) or 2 liters (adult) of water per day, 1-day assessments of 0.2 mg/l for a 10 kg child and 0.7 mg/1 for a 70 kg adult were calculated.

Ten-day assessments were calculated based on a NOAEL of 0.5 mg/kg/day for increased kidney weights in a 90-day feeding study with DBCP in rats (Torkelson, T.R. et al. 1961. Toxicologic Investigations of 1,2-dibromo-3-chloropropane. Toxicol. Appl. Pharmacol. 3:545). Using an uncertainty factor of 100 and consumption of 1 liter (child) or 2 liters (adult) of water per day, 10-day assessments of 0.05 mg/l for a 10 kg child and 0.175 mg/l for a 70 kg adult were calculated.

A provisional AADI was not determined for DBCP due to insufficient data. The taste and odor threshold for DBCP in water has been reported to be 0.01 mg/l in the literature.

The NAS (*Drinking Water and Health*, 1977 and 1981. Vols. I and IV) did not calculate a Suggested-No-Adverse-Response-Level (SNARL) for DBCP. They felt that it would be premature to calculate a SNARL for pure DBCP since the contaminants in technical DBCP could be responsible for toxicological effects in animals and humans.

DBCP has been shown to result in reverse mutations in *Salmonella typhimurium*, recessive lethal mutations in *Drosophila melanogaster*, dominant lethal mutations in rats and chromosomal damage in rats and cultured Chinese hamster cells.

DBCP has been studied for carcinogenicity in mice and rats by oral and inhalation exposure and in mice by dermal application. A National Cancer Institute bioassay (NCI, 1977. Bioassay of Dibromochloropropane for Possible Carcinogenicity. NTIS PB279–472) reported highly significant dose-related incidences in rats of squamous-cell carcimoma of the forestomach of males and females and mammary adenocarcinoma in females receiving gavage doses of 10.7 and 20.7 mg/kg/day. Significantly increased incidences of squamous-cell carcinoma of the forestomach of male and female mice

were found at doses of 78.6 to 156.4 mg/kg/day.

A chronic dietary carcinogenicity study (Hazelton Laboratories America, Inc. 1977. One Hundred Four-Week Dietary Study in Rats; 1,2-dibromo-3-chloropropane (DBCP). Final report. Unpublished report submitted to Dow Chemical Co., Midland, MI. Oct. 29, 1977) reported that male and female rats, at a dose of 2.0 mg/kg/day, as estimated in U.S. EPA, 1979, 44 FR 65135, exhibited significantly increased incidences of carcinoma of the renal tubules, hepatocellular carcinomas and squamous-cell carcinoma of the stomach. DBCP has been shown to result in increased incidences of nasal cavity tumors in mice through inhalation exposure.

The IARC have classified DBCP in Group 2B; inadequate evidence for carcinogenicity in humans and sufficient evidence for carcinogenicity in animals. DBCP has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogenic Risk Assessment, because there are results in studies in animals (rats and mice).

Based upon the tumor incidence for liver, kidney and stomach in rats from the chronic dietary carcinogenicity study discussed above, CAG has estimated the possible carcinogenic risk of lifetime exposure to DBCP for a person consuming 2 liters of water per day. This risk estimate is shown in Table 13.

The Shell Oil Company (Health Effects Evaluation and Risk Assessment of DBCP submitted to Criteria and Standards Division, Office of Drinking Water, EPA, Dec. 1983) has derived risk estimates based on the tumor incidence for liver, kidney and stomach in rats from the same study. Using the geometric mean of five models (probit, logit, Weibull, gamma multi-hit and multi-stage) and three dose scaling factors (mg/kg, ppm, and mg/m^3) for each data set, the Shell Oil Company calculated risks from lifetime exposure to DBCP in drinking water. These risk estimates are as follows:

- 4.6×10^{-6} from lifetime exposure to DBCP based on male rat data.
- 2.2×10^{-14} from lifetime exposure to DCBP based on female rat data.
- 3.7×10^{-5} from one-seventh lifetime exposure to 100 ppb DBCP based on male rat data.
- 1.5×10^{-7} from two-seventh lifetime exposure to 100 ppb DBCP based on male rat data.

The available data indicate that DBCP has non-carcinogenic and carcinogenic effects in animals. Based on potential adverse health effects and occurrence and potential occurrence in drinking water, EPA is proposing to regulate DBCP. The RMCL will be based upon carcinogenic effects and an RMCL of zero is proposed.

Question for Comment:

1. Is there adequate evidence indicating that the contaminants in DBCP account for the toxicity of the compound?

7. o-, m-Dichlorobenzene

o- and m-Dichlorobenzene (CAS #s 95-50-1, 541-73-1) are solvents with low vapor pressures. o-Dichlorobenzene is used primarily in the production of organic chemicals, including pesticides and dyes. It also has direct solvent and pesticidal uses.

Releases of o-dichlorobenzene to air were estimated to be between 118 and 206 kkg in 1963. Industrial losses of m-dichlorobenzene were reported to be 0.185–0.608 kkg/year in 1983. Isomers of dichlorobenzene appear to vaporize rapidly from surface waters, despite their low vapor pressures, and are expected to degrade slowly in the environment.

Analytical Methods. Analytical methods available for analyzing o- and m-dichlorobenzene in drinking water include the purge and trap-gas chromatography and the purge and trap-gas chromatography/mass spectrometry techniques.

Human Exposure. Data on dichlorobenzene in the U.S. food supply are limited. Ortho- and m-dichlorobenzene have been reported in fish from the Great Lakes (0.3–3.0 μg/kg). In one study reported in 1980, 42 samples of milk from nursing mothers in New Jersey, Pennsylvania, Louisiana and West Virginia were found to contain a mean level of 9 μg/ml of dichlorobenzene isomers. All samples were positive for dichlorobenzene with a maximum level of 68 μg/ml. The highest levels reported in the study were found in samples from New Jersey and Louisiana.

Data indicating the level of o- and m-dichlorobenzene in ambient air are available from studies conducted in many States. From the median values of these data, it is estimated that rural/remote, urban/suburban and source dominated dichlorobenzene in ambient air approximate 0.0, 6.6 and 350 ng/m^3, respectively. The estimated respiratory intake for the adult male is expected to vary between zero and 6.2 μg/kg/day. Respiratory intake for formula-fed infants could vary between 0 and 4.3 μg/kg/day.

Median values of data also indicatre that rural/remote, urban/suburban, source dominated and maximum levels of m-dichlorobenzene in ambient air approximate 0.0, 0.036, 0.56 and 16 μg/m^3, respectively. The estimated respiratory intakes for the adult male and formula-fed infant can vary between 0–5.3 and 0–3.7 μg/kg/day, respectively.

Using data for surface water and ground water supplies, it is estimated that 99.3 percent of the population served by public drinking water systems are receiving water with no o-dichlorobenzene or levels less than 0.5 μg/l and that 0.7 percent may be exposed to levels of o-dichlorobenzene in drinking water at or above 0.5 μg/l. The vast majority of cases of drinking water contamination is in surface water supplies. m-Dichlorobenzene was not detected in the Ground Water Supply Survey. o-Dichlorobenzene has been detected in wastewaters and hazardous wastes, is mobile in runoff and soils and large amounts are produced and used across the country.

Health Effects. The principal toxic effects of o-dichlorobenzene in humans and other animals from acute and longer-term exposures include central nervous system depression, blood dyscrasias, lung, kidney and liver damage. Similar data are not available for m-dichlorobenzene. However, based upon the results of a few studies in short-term assay systems, the meta-isomer appears to be similar in toxicity to the ortho-isomer (apparently, not showing greater toxicity). Therefore, the short-term assessments developed for o-dichlorobenzene also will be used for m-dichlorobenzene.

No satisfactory does-response data exist from which to derive a 1-day assessments for either o- or m-dichlorobenzene. It is recommended that, for this duration of exposure, the 10-day level be applied.

The 10-day assessments were derived from results of mouse and rat subchronic gavage studies (Battelle-Columbus, 1978c. Subchronic Toxicity: Ortho-dichlorobenzene. $B_6C_3F_1$ mice. Unpublished report; Battelle-Columbus, 1978i. Subchronic toxicity: Ortho-dichlorobenzene. Fischer 344 rats. Unpublished report). Treated mice and rats received single doses of 0, 30, 60, 125, 250 or 500 mg/kg/day in oil, five days/week, for 90 days. A NOAEL of 125 mg/kg/day was identified for the mouse as well as the rat. Using this NOAEL, applying an uncertainty factor of 100 based upon an animal study in which a no-effect level was identified, a factor of 5/7 to account for conversion from a 5 day/week dosing regimen to a 7 day/week and assuming consumption of 1 liter of water per day, a 10-day assessment for the 10 kg child of 8.9 mg/

l was derived. A 10-day assessment of 31.2 mg/l for the 70 kg adult, who is assumed to drink 2 liters of water per day, also was derived.

The data base selected for derivation of the provisional AADI for o-dichlorobenzene was the subchronic gavage studies in rats and mice described above for the deriviation of the 10-day assessments. Using the NOAEL of 125 mg/kg/day, an uncertainty factor of 1000 based upon an animal study of less than lifetime exposure, a factor of 5/7 to account for conversion from a 5 day/week dosing regimen to 7 day/week and consumption of 2 liters of water per day, a provisional AADI of 3.12 mg/l was determined.

The dichlorobenzenes possess mutagenic activity in certain test systems. Neither were positive in the Ames/*Salmonella* or *E. coli* WP2 mutagenicity assay systems. However, m-dichlorobenzene, both with and without metabolic activation, increased mitotic recombination in *S. cerevisiae*. The orthoisomer was shown to produce abnormal mitotic division in the union, *Allium cepa*. Both o- and m-dichlorobenzene were shown to interact with and damage bacterial DNA in the *E. coli* W3110 polA$^+$/p3478 pol A$^-$ differential toxicity assay system.

o-Dichlorobenzene has been tested by gavage for carcinogenic potential in rats and mice in the NTP Bioassay program (NTP, 1982. Draft Technical Report on the Carcinogenesis Bioassay of 1,2-dichlorobenzene (CAS # 95–50–1) in F344/N rats and $B_6C_3F_1$ Mice (Gavage Study). Draft report). A draft report of the results suggests that o-dichlorobenzene was not carcinogenic under the test conditions. This is a preliminary assessment and no final determination has been made on the carcinogenicity of o-dichlorobenzene. o-Dichlorobenzene has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon the preliminary results of NTP bioassay. The IARC classified o-dichlorobenzene in Group 3; inadequate evidence of carcinogenicity in humans, inadequate evidence for carcinogenicity in animals and inadequate evidence of activity in short-term tests. m-Dichlorobenzene has not been tested for carcinogenicity and thus has also been classified in EPA's Group D.

EPA's ambient water quality criterion (U.S. EPA. 1980. Ambient Water Quality Criteria for Dichlorobenzene. 440/5–8–039) for o-dichlorobenzene is 2.6 mg/l, based upon the NOAEL of 18.8 mg/kg identified in the 1958 Hollingsworth, et al., study (Toxicity of o-dichlorobenzene: Studies on Animals and Industrial Experience. AMA Arch. Ind. Hlth. 17(1):180–187). The WHO proposed drinking water guideline for the ortho- isomer is 0.3 μg/l, based upon organoleptic considerations. The NAS Safe Drinking Water Committee recommended a tentative chronic SNARL of 0.3 mg/l for the orthoisomer, using the lowest dose (60 mg/kg) in the carcinogenicity bioassay (NTP, 1982. See above) and assuming that a 70 kg adult consumes 2 liters of water per day, an uncertainty factor of 1000 and a factor of 5/7, with 20 percent contribution of exposure from water (*Drinking Water and Health*, 1983. Vol. III).

The ambient water quality criteria for o-dichlorobenzene was based upon an older study with a lower NOAEL than was used to develop the provisional AADI, while the WHO guideline did not consider health effects in the derivation of the number. The NAS SNARL was based upon a chronic study which only examined one parameter, while the subchronic study upon which the provisional AADI was based examined many parameters.

The odor thresholds for the dichlorobenzenes in water range from 0.01 to 0.03 mg/l.

Exposure to ortho-dichlorobenzene at high dose levels results in a variety of toxic effects, including central nervous system depression, kidney and liver damage. Because there is also sufficient occurrence potential in drinking water, a Revised Regulation will be proposed and the RMCL will be based upon non-carcinogenic effects. An RMCL of 0.62 mg/l is proposed for ortho-dichlorobenzene based upon a provisional AADI of 3.12 mg/l and assuming 20 percent contribution to total exposure via drinking water. An RMCL is not being proposed for meta-dichlorobenzene due to the lack of long-term compound-specific toxicity data. The only data available on the similarity of toxicity between ortho- and meta-dichlorobenzene consists of data from short-term systems. This data was not considered to be sufficient to propose an RMCL for the meta- isomer based upon the toxicity of orthodichlorobenzene. In addition, the potential for contamination of drinking water supplies by meta-dichlorobenzene appears to be remote and lower than the potential for either the ortho- or the para-isomer.

Question for Comment:

1. Would an appropriate approach be to develop an RMCL for m-dichlorobenzene based upon the toxicity data on o-dichlorobenzene?

8. cis- and trans-1,2-Dichloroethylenes

1,2-Dichloroethylene (CAS # s 156–59–2, 540–59–0) also known as acetylene chloride, is a solvent consisting of a mixture of cis- and trans-isomers. Their proportion varies depending on production conditions. The cis- and trans-isomers have vapor pressures of 180 and 265 mm Hg at 20°C, respectively, and water solubilities of 3.5 and 6.3 g/l, respectively. 1,2-Dichloroethylene is used as a low-temperature extraction solvent for organic materials, and as a chemical intermediate in the synthesis of other compounds. The principal source of these dichloroethylenes in drinking water appears to be from in situ transformations from other chlorinated hydrocarbons.

Analytical Methods. Analytical methods available for analyzing cis- and trans-1,2-dichloroethylene in drinking water include the purge and trap-gas chromatography and the purge and trap-gas chromatography/mass spectrometry techniques.

Human Exposure. No data are available on levels of 1,2-dichloroethylene in the U.S. food supply.

Little data are available on the level of trans-1,2-dichloroethylene in air. Limited sampling at one site resulted in the detection of levels around 4 μg/m^3. Ambient air monitoring for the cis-isomer is available from 10 States. dominated, and maximum levels of cis-1,2-dichloroethylene in ambient air approximate 0.0, 0.27, 1.2 and 27 μg/m^3, respectively. Using these data, estimated respiratory intake for the adult male will vary between zero in rural areas to 8.9 μg/kg/day following exposure at maximum levels. Respiratory intake for formula-fed infants would vary between zero and 6.2 μg/kg/day.

Using combined data for surface water and ground water supplies, up to 2.2 percent of the U.S. population is estimated to be receiving water containing >0.5 μg/l of 1,2-dichloroethylene, and 0.2 percent of the population could be receiving drinking water with 1,2-dichlorethylene levels greater than 20 μg/l.

Health Effects. The principal toxic effects of cis- and trans-1,2-dichloroethylene following acute exposure are upon the liver and kidney. In addition, these compounds possess general anesthetic and narcotic properties at exposure levels above those at which liver and kidney effects are seen. No data are available following longer-term exposures.

One-day assessments for cis-1,2-dichloroethylene were derived from an animal study (Jenkins, L.J., Jr., M.J. Trabelus and S.D. Murphy. 1972. Biochemical Effects of 1,1-Dichloroethylene. Toxicol. Appl.

Pharmacol. 23:501–510). In this study, the authors identified what is interpreted to be a LOAEL. In measuring levels of three liver enzymes and two plasma enzymes, all indicators of liver function, the investigators showed that a single 400 mg/kg oral dose to the rat produced a significant change only in liver alkaline phosphatase, while the levels of the other four enzymes were not affected significantly. The 1-day assessment for the 10 kg child of 4.0 mg/l is derived from the LOAEL of 400 mg/kg, using an uncertainty factor of 1000 since a NOAEL was not determined and an assumed consumption of one liter of water per day. A comparable 1-day level for the 70 kg adult would be 14 mg/l, assuming the ingestion of 2 liters of water per day.

No satisfactory dose-response data are available from which to derive 10-day assessments for cis-1,2-dichloroethylene. Evaluation of the available toxicological data on cis-1,2-dichloroethylene and 1,1-dichloroethylene suggests that a ten-day assessment can be derived from data in the 90-day drinking water study in rats with 1,1-dichloroethylene (Rampy, et al., 1977). A NOAEL of 100 ppm (10 mg/kg/bw) was identified in this study. Applying an uncertainty factor of 100 and assuming consumption of 1 liter of water per day, the ten-day assessment for the 10 kg child would be 1 mg/l. A comparable ten-day level for the 70 kg adult would be 3.5 mg/l, assuming the ingestion of 2 liters of water per day.

One-day assessments for trans-1,2-dichloroethylene were derived from an animal study (Freundt, K.J., G.B. Liebalt and R. Liberwirth. 1977. Toxicology Studies on trans-1,2-Dichloroethylene. Toxicol. 10:131–139). This study identified a NOAEL of 200 ppm inhaled by mature female rats over a single 8-hour exposure period. This exposure resulted in slight liver effects in one of six animals, as observed histologically. No changes were observed in several serum biochemical parameters. A total absorbed dose of 27.2 mg/kg was estimated by converting ppm into mg/m^3 (200×3.97) and multiplying by 8 hours' exposure, assuming that 30 percent of the exposure dose was absorbed, then dividing by 70 kg. The 1-day assessment for the 10 kg child of 2.7 mg/l was derived by applying an uncertainty factor of 100 to the total absorbed dose (in mg/kg) and assuming consumption of 1 liter of water per day. A 1-day assessment of 9.45 mg/l for the 70 kg adult would be derived in the same manner, but, assuming a consumption of 2 liters of water per day.

No satisfactory dose-response data are available from which to derive 10-day assessments for trans-1,2-dichloroethylene. Thus, it has been determined that, in the absence of compound-specific data, the data for 1,1-dichloroethylene used above for the calculation of the 10-day assessments for the cis-isomer are appropriate for the trans-isomer, as well. Therefore, the 10-day assessment for the 10 kg child would be 1 mg/l, and, for the 70 kg adult, 3.5 mg/l.

An AADI for the 1,2-isomers of dichloroethylene could not be developed from compound-specific data since these data do not exist at this time. Two options are available. The first is to propose no AADI at all. The second is to apply an AADI developed from data on 1,1-dichloroethylene. The available information from shorter term exposures to all three of these compounds suggests that the non-carcinogenic toxicity induced by the 1,2-isomers is likely to be no more severe than that of 1,1-dichloroethylene. Since the endpoints of non-carcinogenic toxicity to all three dichloroethylenes are essentially identical, applying the AADI developed for 1,1-dichloroethylene to the 1,2-isomers may even result in an added margin of safety.

The study selected for the derivation of the AADI was a two-year chronic toxicity/oncogenicity study in which male and female rats were given concentrations of 0, 50, 100 or 200 mg/l l, l-dichloroethylene in their drinking water (Quast, et al., 1983. A Chronic Toxicity and Oncogenicity Study in Rats and Subchronic Toxicity Study in Dogs on Ingested Vinylidene Chloride. Fund Appl. Toxicol. 3:55–62). In the highest dose group, significant microscopic changes were noted in the livers of animals of both sexes. Minimal hepatocellular swelling and fatty changes were detected in female rats at all dose levels. An AADI of 0.35 mg/l was determined using a LOAEL of 100 mg/l (or 10 mg/kg), and uncertainty factor of 1000 based upon an animal study with the NOAEL not identified, and consumption of 2 liters of water per day.

Both cis- and trans-l, 2-dichloroethylene were non-mutagenic when assayed with *E. coli* K12 at similar concentrations use for l,l-dichloroethylene at which the latter was found to be mutagenic (Griem, et al. 1975. Mutagenicity *In Vitro* and Potential Carcinogenicity of Chlorinated Ethylenes as a Function of Metabolic Oxirane Formation. Biochem. Pharmacol. 24:2013–2017). Cis-, but not trans-1,2-dichloroethylene was found to be mutagenic in the host-mediated assay using *Salmonella* tester strains in mice (Cerna, M. and H. Kyenova. 1977. Mutagenic Activity of Chloroethylenes Analyzed by Screening System Tests. Mut. Res. 46:214 Abst.). The same authors observed that the cis- isomer also produced chromosomal aberrations in mouse bone marrow cells following intraperitoneal injections.

No long-term studies have been carried out on the carcinogenic potential of cis- and trans-1,2-dichloroethylene and thus both isomers have been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogenic Risk Assessment.

Exposure to cis- and trans-1,2-dichloroethylene at high dose levels results in liver and kidney effects. Since there is widespread occurrence of these contaminants, EPA proposes to regulate them. The proposed RMCL of 0.07 mg/l is based upon an AADI of 0.35 mg/l for both cis- and trans-1,2-dichloroethylene effects derived from data on 1,2-dichloroethylene assuming 20 percent of the exposure is via drinking water.

Question for Comment:

1. In the absence of compound-specific data, is it reasonable to develop an AADI for cis- and trans-1,2-dichloroethylene from toxicity data on 1,1-dichloroethylene?

9. 1,2-Dichloropropane

1,2-Dichloropropane (propylene dichloride; CAS #78–87–5) is a solvent and a pesticide. United States production of 1,2-dichloropropane was approximately 77 million pounds in 1980. Primary uses of 1,2-dichloropropane include: soil fumigation for nematodes and other insects; solvent for metal degreasing, fats, oils, waxes, gums, and resins; intermediate for perchloroethylene and carbon tetrachloride; lead scavenger for anti-knock fluids; and in dry cleaning fluids.

Analytical Methods. Analytical methods available for analyzing 1,2-Dichloropropane in drinking water include the purge and trap-gas chromatography and the purge and trap-gas chromatography/mass spectrometry techniques.

Human Exposure. No data were available on the levels of 1,2-dichloropropane in ambient air or in food.

1,2-Dichloropropane was found in 6 of 466 randomly sampled drinking water systems in the GWSS. The mean level found was 3.7 ug/l. In non-randomly selected samples, 1,2-dichloropropane was observed in 7 out of 479 systems with a mean concentration of 3.7ug/l. High concentrations have been reported

in cases of contaminated ground water. 1,2-Dichloropropane was found in 66 out of 410 drinking water wells in several counties throughout California between 1979 and 1983. 1,2-Dichloropropane has also been detected in wells in New York.

1,2-Dichloropropane has been identified at one hazardous waste site in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of 1,2-dichloropropane ranged from 74 ug/l in soil to 1800 ug/l in runoff.

Health Effects. The principal target organ for 1,2-dichloropropane toxicity appears to be the liver. Centrilobular necrosis, liver congestion and hepatic fatty changes have been reported in animals. Effects on the kidneys and lungs have also been reported in animal studies. There are insufficient toxicological data available in the scientific literature to calculate a 1-day assessment for 1,2-dichloropropane. The 10-day assessment is recommended to be applied to a 1-day exposure.

Ekshtat, et al. (1975. Study of the Cumulative Properties of Substances at Different Levels of Activity. Uch.Zap.-Mosk. Nauchno-Issled. Inst. Gig. 22:46–48.) reported the results of orally administered 1,2-dichloropropane at dose levels of 8.8, 44 or 220 mg/kg for 20 days. The investigators observed disturbances in the animals' protein formation, hepatic enzyme levels and lipid metabolism. The NAS (1979) in a request from the Office of Drinking Water provided a 7-day Suggested-No-Adverse-Response-Level (SNARL) for 1,2-dichloropropane based on the Ekshtat, et al. (1975) study in rats. A LOAEL of 8.8 mg/kg/day was used to derive a 7-day level for a 70 kg adult consuming 2 liters water/day. The NAS SNARL can be used as an interim ten-day assessment as well. The 10-day level is derived using 8.8 mg/kg/day as the LOAEL divided by an uncertainty factor of 1000 (because data are limited and incomplete). For a 70 kg adult consuming 2 liters of water per day, the 10-day number is 0.3 mg/1. For a 10 kg child consuming 1 liter of water per day, the 10-day number is 0.09 mg/l.

There are insufficient data available to calculate a provisional AADI for 1,2-dichloropropane.

Mutagenicity studies have shown that at high concentrations 1,2-dichloropropane induces base-pair substitutions in *Salmonella typhimurim* and induces sister chromatid exchanges or chromosome aberrations in Chinese hamster ovary cells, with or without S9 metabolic activation. In a carcinogenesis bioassay of 1,2-dichloropropane conducted by the National Toxicology Program (NTP Draft Report, 1982), rats were administered 1,2-dichloropropane in corn oil by gavage. In their draft report, the NTP reported significant increases in non-neoplastic liver lesions (foci of clear cell change, centrilobular necrosis) and mammary gland adenocarcinomas in female rats, but treatment related non-neoplastic or neoplastic effects were not observed in male rats.

In a NTP mice study (NTP Draft Report, 1982), non-neoplastic liver lesions were observed in male mice only, but hepatocellular adenomas were increased in both male and female mice. Under the conditions of these studies, 1,2-dichloropropane was considered to be carcinogenic for male and female mice and the effects of 1,2-dichloropropane in rats were considered equivocal. It should be noted that these results are reported in the draft NTP report and the study is currently being audited. The final results may change when the audit is completed and reported by the NTP.

EPA's CAG have derived estimates of risk of daily exposure to 1,2-dichloropropane based upon the NTP mice study. As previously noted, these results are reported in the draft NTP report and the final results may change. The CAG risk estimates are summarized in Table 13.

The EPA (1980) concluded that data regarding the toxicity of 1,2-dichloropropane were insufficient for the derivation of an ambient water quality criterion for the protection of human health.

1,2-Dichloropropane has been classified in EPA's Group C, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon one positive study (NTP Draft Report, 1982) in mice. Thus, 1,2-dichloropropane has been placed in Regulatory Category II and the RMCL will be set at a non-zero level based upon the 10^{-5} risk level. The reason for using a risk level is because the chronic toxicity data are extremely limited and an AADI has not been established for 1,2-dichloropropane. The 10^{-5} level was used because of the quality of the bioassay data which have not been validated.

Exposure to 1,2-dichloropropane has been shown to result in adverse health effects. For this reason and because there is sufficient occurrence in drinking water, a regulation will be proposed. 1,2-Dichloropropane is classified as a possible carcinogen and an RMCL of 6 μg/l is proposed, based upon the 10^{-5} cancer risk level as calculated by EPA's CAG.

Questions for Comment:

1. Are there data available on the toxicology of 1,2-dichloropropane which may be used for the derivation of a provisional AADI?

2. Should 1,2-dichloropropane be classified in EPA's Group C? What should be the basis for the RMCL for this compound?

10. 2,4-D

2,4-D (2,4-Dichlorophenoxyacetic acid; CAS #94–75–7; current MCL is 0.1 mg/l) is a systemic herbicide used to control broadleaf weeds. 2,4-D is sold as a variety of salts, esters and other derivatives which are very soluble in water. 2,4-D and its derivatives undergo both chemical and biological degradation when released to the environment. Soil residues break down in approximately six weeks and repeated application usually does not lead to accumulation. Phenoxy herbicides undergo photolysis and bacterial degradation.

Nearly 60 percent of the domestically available 2,4-D is used on agricultural crop sites. The remainder is used on range and pasture land, industrial and commercial sites, lawns and turf, forests and in water. 2,4-D is currently registered for aquatic weed control in ponds, lakes, reservoirs, marshes, bayous, drainage ditches, canals, rivers and streams.

Analytical Methods. Analytical methods available for analyzing 2,4-D in drinking water include the derivatization gas chromatography technique.

Human Exposure. In the 1970–73 FDA total dietary studies for adults, four samples of leafy vegetables contained residues of 2,4-D in the range of 10–130 ug/kg, and one potato composite sample was found to contain 14 ug/kg. In the 1975–76 total dietary studies for infants and toddlers, one positive sugar and adjunct sample (25 ug/kg) was identified in the toddler food analysis. No residues were found in the infant food analysis. FDA's compliance reports showed that 9 out of 11 food samples were positive for 2,4-D in FY 78, 5 out of 39 samples were positive in FY 80, and 1 out of 10 samples was positive in FY 82.

2,4-D has been reported in ambient air samples from cities in New York and Utah at levels as high as 4 ug/m^3. Thirty percent of the ambient ash air samples taken in western Canada in 1976 were found to contain 2,4-D levels above 0.1 ug/m^3.

2,4-D has been detected in drinking water in four States. In the NORS, one

large surface water system was found to contain detectable levels of 2,4-D (0.04 ug/l. In the NSP, once surface water system contained 2,4-D (1.1 ug/l). None of the surface water systems sampled uring the RWS contained 2,4-D in excess of the minimum quantification limit of 0.01 ug/l. National compliance reports for surface water systems sampled for 2,4-D were below the MCL. Concentrations of approximately 0.025 ug/l 2,4-D have been occasionally detected in public water supplies by State agencies. 2,4-D was detected in 2.4% of surface water monitoring stations in the USGS/EPA Pesticide Monitoring Network.

2,4-D has been detected in many surface and ground waters. The compound has been detected in waste waters and hazardous wastes, is mobile and widely used on many crops.

There are insufficient data available to make reliable estimates of total human intake of 2,4-D from drinking water, food, and air. Assuming that drinking water concentrations vary from 0–10 ug/l, and assuming that air levels range from 0.001–0.05 ug/m^3, the estimated total intake from these two sources could range from 0.00033–0.45 ug/kg/day for the adult male and from 0/00023–0/54 ug/kg/day for the formula fed infant.

Health Effects. Short-term exporsure to 2,4-D at high doses by the oral route or injuction by various routes result in progressive symptoms so muscular incoordination, hindquarter paralysis, stupor, coma and death in animals.

One-day assessments, were derived from an animal study (Hill, E.V. and H. Carlisle, 1947. Toxicity of 2,4-D for Experimental Animals. J. Ind Hyg. Toxicol. 29:85–95). In this experiment, groups of six guinea pigs that were administered 10 doses of 50 or 100 mg/day 2,4-D sodium salt by gavage for 12 days did not develop characteristic evidence of intoxication (i.e)., muscular signs) or mortality. If it is assumed that the guinea pigs weighed 0.3 kg (the reported approximate weight in the single dose studies), the NOAEL of 50 mg/day corresponds to a daily dose of 138.9 mg/kg/day; the equivalent dose of 2,4-D acid is 126.3 mg/kg/day. Although symptoms or signs of intoxication were not specifically associated with this exposure, these criteria of toxicity are still too insensitive to justify using 126.3 mg/kg/day as an animal NOAEL. Using 126.3 mg/day as a LOAEL, an uncertainty factor of 1000 based upon an animal study with a LOAEL and consumption of 1 liter (child) and 2 liters (adult) of water per day, 1-day assessments of 1.1 mg/l and 3.85 mg/l were determined for the child and the adult, respectively.

An animal study (Rowe, V.K. and T.A. Hymas, 1954. Summary of Toxicological Information on 2,4-D and 2,4,5-TP Herbicides and on Evaluating the Hazards to Livestock Associated with Their Use. Am. J. Vet. Res. 15:622–629) was used to develop 10–day assessments. In this study, investigators administered 0, 100, 300 or 1000 ppm 2,4-D in the diet to group of five young female rats for 114 days. If it is assumed that young rats consume 10 percent of their body weight in food per day, the corresponding daily doses would be 0, 10, 30 and 100 mg/kg/day. No effects (same parameters as in the 4 week gavage study) were found at 10 or 30 mg/kg/day, but 100 mg.kg/day produced "excessive mortality" with depressed growth rate, slightly increased liver weights and slight cloudy swelling of the liver. Using a NOAEL of 30 mg/kg/day, an uncertainty factor of 1000 based upon an animal study and consumption of 1 liter (child) and 2 liters (adult) of water per day, 10-day assessments of 0.30 mg/l and 1.1 mg/1 were determined for the child and adult, respectively.

The NAS (*Drinking Water and Health*, 1977. Vol. I) has calculated an ADI for 2,4-D based upon a 2-year feeding study (Hanson, et al. 1977. Toxicology and Applied Pharmacology 20:22–129) in dogs in which 12.5 mg/kg/day was selected as the NOAEL. Using this NOAEL, an uncertainty factor of 1000 based upon an animal study and assumption of an average daily intake of 2 liters of water per day, an ADI of 0.0125 mg/kg/day was calculated.

Inconsistencies and inadequacies in the 2,4-D toxicity data base have been recognized by both EPA and its Scientific Advisory Panel. For example, the inconsistencies consist of varying effects seen at different dose levels in different studies. In order to resolve the inconsistencies and inadequacies, the Agency has taken action under FIFRA 3(c)(2)(B) to require 2,4-D registrants to update and complete the 2,4-D toxicity data base. Some of the required studies have been completed and some are ongoing. As a result of the Panel's recommendations, and the 3(c)(2)(B) notice, a 90-day range-finding study was performed as a preliminary to a 2-year feeding study. The range-finding study (Document Accession No. 251473) identified a NOAEL of 1 mg/kg body weight with the liver and kidney as target organs. Preliminary data from the chronic study support the 1 mg/kg NOAEL. Assuming that at the end of the 2-year experiments there is no change in the NOAEL, an uncertainty factor of 100 can be applied to derive a provisional AADI of 0.35 mg/l.

2,4-D may have mutagenic activity in certain systems; however, the general lack of positive genotoxic effects *in vivo* for mammalian assays may indicate that sufficient levels of 2,4-D are not able to reach the target tissues. No information is available on mammalian mutagenicity testing conducted with esters of 2,4-D; these forms could theoretically show higher levels of penetration into target cells.

Available data from laboratory animals have not provided a sufficient demonstration of carcinogenicity of 2,4-D, although increased tumor production is suggested. This questions cannot be adequately resolved until more compelling evidence is available from well designed bioassays. 2,4-D has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data from animal studies.

EPA's MCL for 2,4-D in drinking water, under the National Interim Primary Drinking Water Regulations, is 0.1 mg/l. This standard is based upon a NOAEL of 8 mg/kg/day, an uncertainty factor of 500 and the assumption that 20 percent of the total intake is via drinking water. New studies have determined a NOAEL at 1 mg/kg/day.

Exposure to 2,4-D at high dose levels results in kidney damage and skeletal muscle changes. It has also been detected in drinking water. Therefore, an RMCL will be proposed based upon an AADI of 0.35 mg/l for non-carcinogenic effects, assuming 20 percent of total exposure is via drinking water. An RMCL of 0.07 mg/l is proposed.

11. Epichlorohydrin

Epichlorohydrin (1-chloro-2,3-epoxypropane; CAS #106–89–8) is a halogenated alkyl epoxide. It is soluble in water (6.6×10^4 mg/l) and organic solvents. A large fraction of the epichlorohydrin supply is used to make glycerin. Other applications include: use as a major raw material for epoxy and phenoxy resins and flocculants (sometimes used in the production of potable water and foods), solvent for resins, gums, cellulose esters and ethers, paints, varnishes, nail enamels and lacquers (sometimes used to coat interiors of water tanks and pipes); cement for celluloid; curing for propylene-based rubbers; and use as a high wet-strength resin for the paper industry.

Analytical Methods. Analytical methods available for analyzing

epichlorohydrin in drinking water include the direct injection gas chromatography technique.

Human Exposure. No ambient monitoring data are available on human intake of epichlorohydrin from ambient air, food or drinking water supplies. However, epichlorohydrin emissions and public exposure levels were estimated by EPA's Office of Air Quality Planning and Standards, based upon plants that manufacture or use epichlorohydrin in the production of glycerin, epoxy and polyamide resins, elastomers and surfactants. A human exposure model was employed, based upon a 50 km radius around each epichlorohydrin facility, which estimated than approximately 60 persons are exposed to a concentration of 8 $\mu g/m^3$ or greater, approximately 1,000 persons are exposed to a concentration of 1 $\mu g/m^3$ or greater and approximately 70,000 persons are exposed to a concentration of 0.1 ug/m^3 or greater.

Epichlorohydrin is a contaminant of polymers used in the clarification and storage of potable water and in food processing. It has been detected in waste and is considered mobile in water.

Health Effects. Epichlorohydrin is rapidly absorbed following oral, dermal or inhalation exposures. Epichlorohydrin accumulates in the kidneys, liver, pancreas, spleen and adrenals and is excreted via the urine and respiratory tract.

Following acute exposure to epichlorohydrin, toxic effects in the central nervous system, lungs, liver and kidneys have been observed. At the site of application epichlorohydrin is a strong irritant. The major target organs for toxicity following chronic exposure to epichlorohydrin are the nasal turbinates, lungs, kidneys, male reproductive organs and the central nervous system.

A short-term assessment for a 10-day exposure was calculated based on a study in rats (Van Esch, G.J. 1981. Ryksinstitute Voor De Volksgezondheld Bilthoven Rapport. 627805 005) where antifertility effects were observed in males given oral doses of epichlorohydrin for 10 days before mating and through parturition of an F_{1a} generation. Using a NOAEL of 2 mg/kg, an uncertainty factor of 100, and consumption of 1 liter (child) or 2 liters (adults) of water per day, a 10-day assessment of 0.14 mg/l for a 10 kg child and 1-day and 10-day assessments of 0.5 mg/l for a 70 kg adult was calculated. This assessment is also considered protective for a 1-day exposure for the child and adult.

The NAS (*Drinking Water and Health*, 1980. Vol. III) has cited a threshold for odor perception of epichlorohydrin of 0.5 to 1.0 mg/l and a threshold for irritant action of 0.1 mg/l. A human study (Fomin, 1966. Biological Effects of Epichlorohydrin and its Hygienic Significance as an Atmospheric Pollutant Gig. Hyg. Sanit. 31:357–363) reported an odor threshold of 0.3 mg/m^3 for the most sensitive subjects and a subthreshold level of 0.2 mg/m^3.

A provisional AADI was calculated for epichlorohydrin based upon an inhalation study in which male rats were exposed to 100 ppm epichlorohydrin 6 hours/day for 30 days and 10 or 30 ppm epichlorohydrin 6 hours/day, 5 days/week for the lifetime of the rats and inflammation changes in the respiratory tract and kidney lesions were observed (Laskin, S., A.R. Sellakumar, M., Kuschner, N. Nelson, S. LaMendola, G.M. Rusch, et al., 1980. Inhalation Carcinogenicity of Epichlorohydrin in Noninbred Sprague-Dawley rats. J. Natl. Cancer Inst. 65:751–757). Using 2.16 mg/kg/day, as derived from the 10 ppm exposure level, as the LOAEL, an uncertainty factor of 1000 and consumption of 2 liters of water per day, a provisional AADI of 0.076 mg/l was calculated.

The NAS (*Drinking Water and Health*, 1980. Vol. III) calculated 1-day and 7-day SNARLs for epichlorohydrin but did not calculate an ADI or cancer risk numbers.

Epichlorohydrin has been found to be mutagenic in a number of prokaryotic systems and eukaryotic cell cultures. Negative results were reported for the mouse dominant lethal assay and micronucleus assay.

Epichlorohydrin has been found to be carcinogenic following oral and inhalation exposures. Oral exposure produced a dose-dependent increase in forestomach tumors characterized as squamous and basal cell hyperplasia, squamous cell papillomas or squamous cell carcinomas Inhalation exposure produced squamous cell carcinomas in the nasal cavities. The IARC have classified epichlorohydrin in Group 2B; inadequate evidence for carcinogenicity in humans, sufficient evidence for carcinogenicity in animals and sufficient evidence for activity in short-term tests. Epichlorohydrin has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon positive results in several sites in rats.

EPA's CAG has derived estimates of risk from daily exposure to epichlorohydrin in drinking water based upon the incidence of tumors of the forestomach in a study in which rats were given drinking water containing 0, 375, 750, or 1500 mg/l epichlorohydrin for 81 weeks (Kawabata, A., 1981. Studies on the Carcinogenic Activity of Epichlorohydrin by Oral Administration in Male Wistar Rats. J. Amer. Med. Assoc. 32:270–280). The CAG risk estimate is shown in Table 13.

The CAG has also calculated risk estimates (95 percent confidence limits) from lifetime exposure to 10 $\mu g/l$ epichlorohydrin using several different models. These estimates are as follows:

Dose	95% upper confidence limit of additional risks			
	Multi-stage model	One-hit model	Weibull model	Log-Probit model
10 $\mu g/l$	2.6×10^{-4}	3.4×10^{-4}	0	0

The available data indicate that epichlorohydrin has carcinogenic effects in animals. For this reason and because it is likely to be occurring in drinking water due to its use in coatings for drinking water pipes, regulation is proposed. The RMCL will be based upon carcinogenic effects and an RMCL of zero is proposed.

12. Ethylbenzene

Ethylbenzene (CAS # 100–41–4) is a flammable liquid, soluble in water (152 mg/l) and in alcohol, benzene, ether, acetone and other organic solvents. In 1982, the U.S. production totaled 6,656,241,000 pounds. The primary use of ethylbenzene is in the production of styrene.

Analytical Method. Analytical method available for analyzing ethylbenzene in drinking water include the purge and trap-gas chromatography technique.

Human Exposure. No data are available on the levels of ethylbenzene in foods.

Limited data are available on the levels of ethylbenzene in ambient air. Ethylbenzene levels in ambient air have been reported between 2 $\mu g/m^3$–5 $\mu g/m^3$ in various areas.

Ethylbenzene has been observed in 3 out of 466 randomly selected drinking water ground water systems. The mean was 0.87 $\mu g/l$. Ethylbenzene also was detected in 3 out of 479 ground water systems selected non-randomly (0.6%). All three positives were from systems serving less than 10,000 people. The mean was 0.78 $\mu g/l$.

Ethylbenzene has been identified at one hazardous waste site designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability

Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of ethylbenzene ranged from 23 mg/l in drinking water to 13 mg/l in an aquifer.

Health Effects. Ethylbenzene is absorbed readily from the gastrointestional tracts, lungs and skin and can be expected to accumulate in adipose tissue. Urinary excretion of metabolites of ethylbenzene is the predominant route of elimination.

Ethylbenzene is not severely toxic after acute exposure. The major effects following acute and chronic exposure include liver and kidney pathologies and nervous system disorders.

No adequate dose-response data exist via the oral route of exposure from which to derive 1-day assessments. Therefore, the derivation of the 1-day levels was based upon a 100 ppm (435 mg/m^3) NOAEL identified in humans following a single 8-hour inhalation exposure (Bardodej and Bardodejova, 1970. Biotransformation of Ethylbenzene, Styrene and Alpha-Methyl Styrene in Man. Amer. Ind. Hyg. Assoc. J. 31(2):206–209). A total absorbed dose of 20.7 mg/kg was determined, assuming a human respiratory inhalation volume of 20 m^3/day and an absorption efficiency of 50 percent for a 70 kg adult. From this total absorbed dose, a 1-day assessment of 20.7 mg/l was derived for the 10 kg child, assuming consumption of 1 liter of water per day. A 1-day assessment of 72.5 mg/l for the 70 kg adult was derived, assuming consumption of 2 liters of water per day, applying an uncertainty factor of 10, appropriate for use with adequate human data.

Because of the lack of appropriate exposure duration data, the 10-day assessments are derived from the 1-day levels simply by dividing the 1-day numbers by 10 to give estimated 10 values. The resulting 10-day assessment for the 10 kg child is 2.07 mg/l and for the 70 kg adult, 7.25 mg/l.

A provisional AADI was determined based upon a laboratory study in which rats were treated orally at four dose levels, 5 days/weeks for 6 months (Wolf, et al. 1956. Toxicological Studies of Certain Alkylated Benzenes and Benzene. Arch. Ind. Health. 14:387–398). No observable effects were reported in the groups exposed at 13.6 and 136 mg/kg/day, while histopathological changes were evident in groups treated at 408 and 680 mg/kg/day. A NOAEL of 136 mg/kg/day was identified, with an uncertainty factor of 1000 based upon an animal study of significantly less than lifetime duration and a factor of 5/7 to convert from a 5 day/week dosing regimen to a 7 day/week exposure pattern, consumption of 2 liters of water per day factored in, resulting in a provisional AADI of 3.4 mg/l.

Ethylbenzene does not appear to be a mutagen, based upon testing in a limited number of assays with *Salmonella typhimurium* strains. The carcinogenicity of ethylbenzene has not been tested adequately. A long-term carcinogenicity bioassay has been initiated by the National Cancer Institute, but data are not yet available. Ethylbenzene has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate evidence in animals.

EPA's ambient water quality criterion (U.S. EPA. 1980. Ambient Water Quality Criteria for Ethylbenzene. 440/5–80–048) for ethylbenzene of 1.4 mg/l, based upon the TLV and an uncertainty factor of 1000. The provisional AADI was based upon actual toxicological data with an identified NOAEL, in contrast to the ambient water quality criterion which was based on the TLV which is not necessarily based on a NOAEL or toxicology data.

The taste and odor thresholds for ethylbenzene in water are 0.1 and 0.2 mg/l, respectively (Fazzalari, 1978. Odor and Taste Threshold Data, DS–48A. American Society for Testing and Materials. Philadelphia, PA. p. 71).

Ethylbenzene exposure at high dose levels results in liver and kidney effects and the contaminant has been detected in drinking water. Thus, regulation is proposed and an RMCL of 0.68 mg/l is proposed based upon a provisional AADI of 3.4 mg/l for non-carcinogenic effects assuming 20 percent of the exposure is via drinking water.

13. Ethylene Dibromide

Ethylene dibromide (1,2-dibromoethane, EDB; CAS #106–93–4) is a pesticide. Most uses of EDB were canceled in 1984. Citrus quarantine and several very minor uses remain registered. EDB is water soluble (4,500 mg/l) and highly volatile. Recent data suggest that EDB has a half-life of approximately eight years at 20 °C under neutral conditions. More than 90 percent of the annual total production of EDB is used as an additive in leaded gasoline. In addition, EDB has been used as a soil fumigant for soybeans, cotton, peanuts, pineapples and many other fruit and vegetable crops. EDB had been used in post-harvest fumigation of stored grain and spot fumigation of grain milling machinery. Other uses have included the fumigation of field logs and the quarantine fumigation of citrus and other fruits and vegetables, application to beehives and storage vaults and for termite control.

Analytical Methods. Analytical methods available for analyzing EDB in drinking water include the purge and trap-gas chromatography technique.

Human Exposure. Ethylene dibromide has been detected in up to 60 percent of raw grain and 8 percent of grain products at levels as high as 5400 ppb. EDB residues also have been detected on up to 5 percent of the citrus products entering the U.S. food supply.

Ethylene dibromide has been reported in ambient air associated with the use of leaded gasoline. The following median concentrations were estimated for levels of EDB in ambient air: rural/remote areas, 0.0 ng/m^3; urban/suburban areas, 200 ng/m^3; and source dominated areas, 1,500 ng/m^3. Concentrations of EDB in typical urban areas ranged from 80–460 ng/m^3. The highest value detected was 240,000 ng/m^3.

EDB has been found in drinking water and ground water in Hawaii, California, South Carolina, Washington, Connecticut, Massachusetts, Georgia and Florida. Two small community water supplies in one State contained 0.1 and 2.0 μg/l of EDB. Four out of 100 wells sampled in another State contained EDB at levels ranging from 0.02–0.10 μg/l. In addition, levels of EDB ranging from 0.02–560 μg/l were detected in 25 samples of water collected from wells in a third State.

Health Effects. EDB has a high degree of acute toxicity when administered to animals orally, dermally or by inhalation. The target organs affected include the lung, liver, spleen, kidney as well as the central nervous system. Repeated exposure to EDB also may affect the liver, stomach and adrenal cortex along with significant reproductive system toxicity. The testis is particularly sensitive to atrophy and antispermatogenic effects.

No appropriate dose-response data are available on non-carcinogenic effects following exposure to ethylene dibromide from which a 1-day assessment or an AADI could be derived. However, there are data from which a 10-day assessment can be derived. A LOAEL of 7.8 mg/kg/day was identified from a study by ElJack and Hrudka (1979) in which rams were given EDB subcutaneously for 12 consecutive days. Applying a series of uncertainty factors which total 10000 to accommodate for intra- and inter-species extrapolation (100), conversion of a LOAEL to a NOAEL (10) and the potential that the human is closer in sensitivity to the bull than the ram (10), and assuming that the 10 kg child drinks

1 liter of water per day, a 10-day assessment of 0.008 mg/l is derived. The equivalent 10-day assessment for a 70 kg adult would be 0.027 mg/l.

Since there are no duration-specific data available from which to derive a 1-day assessment, it is recommended that the 10-day assessment be used for 1-day as well.

EDB has been shown to be mutagenic *in vitro* in bacteria and eukaryotic cells. Limited evidence suggests that EDB may cause clastogenic effects such as sister chromatid exchanges, chromosomal aberrations and polyploidy.

EDB has been demonstrated to be a potent carcinogen in rats and mice exposed via gavage and inhalation. The IARC have classified EDB in Group 2B; inadequate evidence for carcinogenicity in humans, sufficient evidence for carcinogenicity in animals and sufficient evidence for activity in short-term tests. EDB has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon positive results in studies in rats and mice.

Administration of EDB to rats and mice by gavage for 49–61 weeks produced significantly increased incidences of squamous cell carcinomas of the forestomach, hemangiosarcomas of the circulatory system, hepatocellular carcinomas and liver neoplastic nodules. (NCI, 1978. Bioassay of 1,2-Dibromoethane for Possible Carcinogenicity. NCI Carcino. Tech. Rep. Ser. Co. PB 2888–428). Chronic inhalation exposures produced significantly increased incidences of nasal cavity tumors in rats of both sexes, alveolar/bronchiolar carcinomas or adenomas in mice and nasal cavity tumors in female mice. (NTP, 1982. Carcinogenesis Bioassay of 1,2-Dibromoethane in F344 Rats and $B_6C_3F_1$ Mice (Inhalation Study) NTP–80–28). Significantly increased incidences of circulatory system hemangiosarcomas, pituitary adenomas, tunica vaginalis mesotheliomas and subcutaneous fibrosarcomas also were found in the study.

The NAS (*Drinking Water and Health*, 1980. Vol. III) calculated excess cancer risk estimates for EDB. This estimate was based upon the results of a report (Olson, et al. 1973. Induction of Stomach Cancer in Rats and Mice by Halogenated Aliphatic Fumigants. J. Natl. Cancer Inst. 51:1993–1995) which describes the results of the bioassay conducted by NCI. EPA's CAG (1983) also has estimated lifetime cancer risks for EDB in ground water. These risks were calculated from a model that is essentially the one-hit model with "Weibull" timing. These estimated risks assume consumption of 2 liters of water per day by a 60 kg adult, over a 70 year lifetime and are derived from the gastric tumor response in male rats in the National Cancer Institute gavage study. Subsequently, CAG (1984) modified these estimates to determine risks posed in drinking water to a 70 kg adult, consuming 2 liters of water per day from age one to age 76.

The NAS (1980) and CAG (1984) risk estimates are shown in Table 13.

The available data indicate that EDB has carcinogenic effects in animals. It has also been found in drinking water and therefore it will be regulated. The RMCL will be based upon its carcinogenicity and an RMCL of zero is proposed.

14. Heptachlor and Heptachlor Epoxide

Heptachlor (1,4,5,6,7,8,8'-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene; CAS #76–44–8; expoxide CAS #1024–57–3) is an insecticide. Technical grade heptachlor is a waxy substance which contains chlordane and has a water solubility of 0.056 mg/l at 25 °C. Heptachlor rapidly oxidizes to the epoxide 1,4,5,6,7,8,8'-heptachloro-2,3-epoxy-3a,7,7a-tetrahydro-4,7-methanoindene, which is more stable and more presistent. Most registrations of heptachlor were suspended in 1976.

Prior to 1974, heptachlor was widely used for control of termites, ants, soil insects in agriculture and various insects and on gardens, lawns, turf, and ornamentals. Heptachlor was used extensively for the protection of corn crops in Ohio, Iowa, Missouri, Illinois and Indiana.

In 1974, EPA issued a Notice of Intent to cancel all registered uses of heptachlor except for subsurface control of termites and dipping of roots and tops of non-food plants. In 1978, EPA issued a final order cancelling all registrations of heptachlor subject to the 1974 Notice of Intent to Cancel. Currently, heptachlor is registered only for subsurface control of subterranean termites and dipping of roots and tops of non-food plants.

Analytical Methods. Analytical methods available for analyzing heptachlor in drinking water include the solvent extraction-gas chromatography and solvent extraction-gas chromatography/mass spectrometry techniques.

Human Exposure. In FDA's compliance program report for fiscal year 1977 on pesticides and metals, heptachlor epoxide was detected in 4.7 percent of the samples tested. In the FDA fiscal year 1979 total dietary study for adults, heptachlor epoxide, the metabolite of heptachlor, was detected in 65 percent of the dairy products samples, 50 percent of the meat, fish and poultry samples, 5 percent of the oils and fats samples, 5 percent of the root vegetable samples, and 5 percent of the oils and fats samples. The range of positive values for heptachlor epoxide was 0.2–2 μg/kg. In the infant study, heptachlor epoxide was detected in 50 percent of the whole milk samples, 50 percent of the other dairy and substitutes samples, and 70 percent of the meat, fish, and poultry samples. The range of positive values was 0.2–1 μg/kg for heptachlor epoxide. In the toddler studies for fiscal year 1979, heptachlor epoxide was detected in 50 percent of the whole milk samples, 80 percent of the other dairy and substitutes samples, 70 percent of the meat, fish, and poultry samples, and 10 percent of the oils and fats samples. The range of positive values of heptachlor epoxide in this study was 0.2–20 μg/kg. The U.S. Department of Agriculture reports that 4.7 percent of fat tissue samples from various animals intended for human consumption were found to contain heptachlor in the range of 100–5,000 μg/kg, although the majority of positive values were in the range of 10–100 μg/kg.

Milk supplies have on occasion been found to contain heptachlor epoxide above FDA's action level. Samples of human milk collected in the mid-1970s were found to contain heptachlor epoxide. In 1980-1982, the Oahu milk supply was extensively contaminated by heptachlor epoxide. The levels exceeded 1 ppm in the milk fat and typically exceeded the action level.

In a 1970–72 EPA study of levels of heptachlor in the ambient air of 18 U.S. cities, the maximum level measured was 27.9 ng/m^3. The mean value for all positive samples was 1.0 ng/m^3. Heptachlor was detected in 42 percent of the 2,470 samples collected during the monitoring period.

The results of the Suburban Air Monitoring Program conducted from April to June 1975, showed that all five samples collected from a city in Florida were found to contain heptachlor with a mean concentration of 2.1 ng/m^3 and a maximum value of 3.8 ng/m^3. All five samples collected from a city in Mississippi were found to contain residues of heptachlor. The sample mean was reported as 10.9 ng/m^3, with a maximum reported value of 22.1 ng/m^3.

The maximum level of heptachlor detected in analysis of weekly air samples in the Mississippi Delta during 1972–73 was reported as 0.8 ng/km^3.

Heptachlor has been reported in drinking water. Three wells in one State were found to contain heptachlor; the

range of positive values was 0.01–1.0 μg/l. A rural water supply study conducted in another State showed that 62.5 percent of the samples taken in one county and 45.5 percent the samples taken in another county had concentrations of heptachlor above 0.01 μg/l.

Two out of 22 tap water samples collected in another State reportedly were found to contain heptachlor at levels between 0.005–0.25 μg/l.

Heptachlor has been identified at two hazardous waste sites designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of heptachlor ranged from undetermined in migrating ground water, 38 μg/l in soil to 4800 μg/l in sediments.

Health Effects. Heptachlor epoxide is the major metabolite of heptachlor and is distributed to tissues of animals, with the highest levels detected in adipose tissue. Symptoms of acute heptachlor intoxication include central nervous system disturbances such as tremors, convulsions, paralysis and hypothermia. Lower doses result in microsomal enzyme induction, hyperplasia, hepatic vein thrombosis and cirrhosis in mice.

Ten-day assessments for heptachlor were derived based upon a feeding study (Enan, et al. 1982. Effects of Some Chlorinated Hydrocarbon Insecticides on Liver Function in White Rats. Meded. Fac. Landbouwwet. Rijksuniv. Gent. 47(1):447) in rats for 14 days where a level of 1.0 mg/kg/day (10 ppm) resulted in definitive adverse effects (i.e., evidence of liver damage and altered liver function). Using 1.0 mg/kg/day as the NOAEL, an uncertainty factor of 1000 based upon an animal study and consumption of 1 liter (child) or 2 liters of water (adult) per day, 10-day assessments of 0.01 mg/l for a 10 kg child and 0.035 mg/l for a 70 kg adult were calculated.

There are insufficient toxicological data available to derive a 1-day assessment for heptachlor; however it should be noted that the 10-day numbers would also be protective for the 1-day exposure period. Insufficient data are available to derive 1-day or 10-day numbers for heptachlor epoxide.

A provisional AADI for heptachlor was derived based upon a feeding study (Witherup, et al. 1955. The Physiological Effects of the Introduction of Heptachlor into the Diet of Experimental Animals in Varying Levels of Concentration. Unpublished report cited in Epstein, 1976. Sci. Total Environ. 6:103) in rates for 110 weeks where 0.075 mg/kg/day (1.5 ppm) was identified as a lowest effect level causing increased liver weights of animals. Using 0.075 mg/kg/day as the LOAEL, an uncertainty factor of 1000 based upon an animal study and consumption of 2 liters of water per day, a provisional AADI of 0.0025 mg/l was calculated.

For heptachlor epoxide, a provisional AADI was derived based upon a two-year oral study in dogs (Unpublished. IRDC. 1971. Two-year study Oral Study in Beagle Dogs) where 0.025 mg/kg/day (1 ppm) was identified as the NOAEL. Using 0.025 mg/kg/day as the NOAEL, an uncertainty factor of 1000 for an animal study of less than lifetime duration and consumption of 2 liters of water per day, a provisional AADI of 0.001 mg/l was calculated.

Heptachlor has been tested for mutagenicity in a number of systems. Negative results have been obtained in the bacterial assay in fruit flies, for unscheduled DNA synthesis in rats, mouse and hamster primary hepatocyte cultures and for the dominant lethal assay in mice. Positive results were reported for unscheduled DNA synthesis in transformed human fibroblasts with S-9 activation and in the dominant lethal assay in rats (Cerey, et al. 1973. Effects of Heptachlor on Dominant Lethality and Bone-Marrow in Rats. Mutat. Res. 21:28).

Heptachlor has been studied for carcinogenicity in mice and rats. In one study, statistically significant increased incidences of hepatic carcinoma were determined in a study of heptachlor epoxide at 0, 0.5, 2.5, 5.0, 7.5 and 10.0 mg/kg diet in rats for 108 weeks (Witherup, et al. 1959. The Physiological Effects of the Introduction of Heptachlor Epoxide in Varying Levels of Concentration into the Diet of CFN Rats. Unpublished report cited in Epstein, 1976. Sci. Total Environ. 6:103). In a National Cancer Institute bioassay (NCI. 1977. Bioassay of Heptachlor for Possible Carcinogenicity. NCI Carcinogenesis Tech. Rep. Ser. No. 9), male mice received dietary concentrations of 0, 6.1 and 13.8 mg heptachlor/kg diet and female mice received diets containing 0, 9.0 and 18.0 mg/kg diet. The incidence of hepatocellular carcinomas was statistically significant in the males, while a highly significant dose-related trend was also observed between high- and low-dose females. Heptachlor was not carcinogenic in male and female rats similarly treated with concentrations of 25.7 to 77.9 mg/kg diet.

EPA's CAG has derived estimates of risk of daily exposure to heptachlor in drinking water based upon the incidence of hepatocellular carcinomas in male mice in the National Cancer Institute bioassay. The NAS (*Drinking Water and Health*, 1977., Vol. I) has also estimated cancer risks. The CAG and NAS lifetime risk estimates are shown in Table 13. The IARC have classified heptachlor in Group 3; inadequate evidence of carcinogenicity in humans and limited evidence of carcinogenicity in animals. Heptachlor has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon positive results in studies in mice.

EPA's CAG has also derived risk estimates from daily exposure to heptachlor expoxide in drinking water based upon a feeding study in female rats (Witherup, et al. 1959. The Physiological Effects of the Introduction of Heptachlor Epoxide in Varying Levels of Concentration into the Diet of CFN Rats. Unpublished report cited in Epstein, 1976. Sci. Total Environ. 6:103). The CAG risk estimates are shown in Table 13. The IARC have not classified heptachlor epoxide for carcinogenicity. Heptachlor expoxide has also been classified in EPA's Group B2, based upon positive results in studies in mice and rats.

The WHO recommended an ADI value of 0.5 μg/kg bw for heptachlor or heptachlor epoxide. This recommendation was established by the Joint FAO/WHO Expert Committee on Food Additives. A guideline value in drinking water (1984) of 0.1 μg/l was also recommended by the WHO, based upon this level as one percent of the ADI. A detection and odor threshold value of 0.02 mg/l has been reported in the literature for heptachlor.

The available data indicate that heptachlor and heptachlor epoxide have carcinogenic effects in animals. Since heptachlor epoxide is considered to be a major metabolite of heptachlor and because they have been detected in drinking water, they are proposed for regulation. An RMCL of zero is proposed for both heptachlor and heptachlor expoxide.

Question for Comment:

1. Should a single RMCL or two individual RMCLs be proposed for heptachlor and its metabolite heptachlor epoxide?

15. Lindane

Lindane (gamma is isomer of 1,2,3,4,5,6-hexachlorocyclohexane; CAS # 58–89–9; current MCL is 4 μg/l) is an insecticide registered for commercial and home use. Lindane is the active ingredient in several prescribed shampoos used for the elimination of head lice. Similar preparations are

available for the elimination of fleas and lice on pets and farm animals.

Lindane is slightly soluble in water (7.8 mg/l at 25° C). Despite a low vapor pressure, lindane will volatilize to the atmosphere from soil or water. It is persistent in soils (half-life greater than 100 days), though it does undergo rapid biotransformation under anaerobic conditions.

Analytical Methods. Anayltical methods available for analyzing lindane in drinking water include the solvent extraction gas chromatography technique.

Human Exposure. In 1977, the FDA reported finding lindane residues in 2.1 percent of the food samples tested. In the 1979 total diet study, FDA reported lindane in 12.7 percent of adult food samples with concentrations ranging from trace to 8.0 μg/kg in sugar, meat, fish, poultry, grains, cereal, vegetables and garden fruit. In the same year, 2 percent of the infant food samples and 14.7 percent of toddler food samples were positive for lindane, with concentrations ranging from 0.2 to 2 μg/kg and from 0.2 to 5 μg.kg, respectively.

Tolerances for residues of lindane established by the EPA's Office of Pesticide Programs (OPP) in or on raw agricultural commodities are given below:

- Seven parts per million in or on the fat of meat from cattle, goats, horses, and sheep.
- Four parts per million in or on the fat of meat from hogs.
- Three parts per million in or on cucumbers, lettuce, melons, mushrooms, pumpkins, squash and tomatoes.
- One part per million in or on apples, apricots, asparagus, avocados, broccoli, brussel sprouts, cabbage, cauliflower, celery, cherries, collards, eggplants, grapes, guavas, kale, kohlrabi, mangos, mustard greens, nectarines, okra, onions (dry bulb only), peaches, pears, pepper, pineapples, plums (fresh prunes), quinces, spinach, strawberries and Swiss chard.
- A 0.001 part per million (negligible residue) in or on pecans.

The USDA notes that 0.1 percent of swine samples violated allowable lindane concentrations in a 1980–1983 monitoring study. No lindane residues in excess of the tolerance were found in other meat products examined.

In a 1970–1972 EPA study of 16 U.S. cities, lindane was detected in 68 percent of the ambient air samples. The positive mean value was 0.9 ng/m³ and the maximum value reported was 11.7 ng/m³. In a 1980 EPA study monitoring 10 locations in the U.S., 0.8 percent of the samples contained detectable levels of lindane, with a mean level of 0.1 ng/m³ and a maximum level of 1.5 ng/m³.

Low levels of lindane have occasionally been found in drinking water. It has been found in drinking water in at least four States. In the National Organics Reconnaissance Survey (NORS), two out of eight surface water systems contained lindane (0.01 μg/l and trace).

National compliance data show that no surface or ground public water systems in the U.S. were reported to be in violation of the MCL for lindane.

In the Rural Water Survey (RWS) 1 out of 71 ground water systems exceeded the minimum quantification limit (0.002 μg/l) for lindane. In the NORS, water samples from the two ground water systems sampled contained lindane, but the levels were below the minimum quantifiable concentration.

Local conditions can lead to drinking water contamination. A rural water supply study in one State reported that 58.3 percent of samples contained levels of lindane greater than the detection limit of 0.01 μg/l.

Lindane has been identified at five hazardous waste sites designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300).

Health Effects. Acute exposure of animals to lindane results in neurological and behavioral effects. Subchronic and chronic studies have shown a variety of effects, including liver hypertrophy, kidney tubular degeneration and interstitial nephritis. The liver and the kidney appear to be the primary target organs for lindane toxicity.

Insufficient data are available to derive a one-day assessment for lindane. A 10-day assessment was based upon a study (Muller, et al. 1981. Electroneurophysiological Studies on Neurotoxic Effects of Hexachlorocyclohexane isomers and gamma-pentachlorocyclohexane. Bull. Environ. Contam. Toxicol. 27:704–706) in which decreased motor conduction velocity was detected in the tail nerve of rats fed lindane for 30 days at 25.6 mg/kg. Ten-day values of 1.2 mg/l for a 10 kg child and 4.3 mg/l for a 70 kg adult were calculated from a NOAEL of a 12.3 mg/kg, with an uncertainty factor of 100 based upon an animal study and consumption of 1 liter (child) or 2 liters (adult) of water per day.

In the absence of an appropriate toxicological data base for a one-day assessment, the ten-day values of 1.2 mg/l for the child and 4.3 mg/l for the adult are recommended for use for 1-day assessments.

A provisional AADI was calculated for lindane based upon a feeding study (Research Consulting Co. Ltd., 1983. OPP Support Document) in which male and female rats were fed pure lindane in the diet at levels of 0, 0.2, 0.8, 4, 20 and 100 ppm for 84 consecutive days. Liver hypertrophy, kidney tubular degeneration, interstitial nephritis and basophilic tubules and other effects were seen at the 20 and 100 ppm levels. Effects were rare and very mild at the 4 ppm level. Using 0.6 mg/kg/day (4 ppm) as the NOAEL, an uncertainty factor of 1000 based upon an animal study of short duration and consumption of 2 liters of water per day, a provisional AADI of 0.01 mg/l was calculated.

Lindane has been tested for carcinogenicity in laboratory animals. Thorpe and Walker (1973, Food and Cosmet. Toxicol. 11:433–442) reported a significant increase in liver tumors in the treated mice relative to the controls (96% in treated males and 95% in treated females, compared to 24% and 23%, respectively, in the controls). In addition, there was evidence of tumor metastases to the lungs in both sexes. In 1977, the NCI (Technical Rep. Ser. No. 14) published the results of a lifetime bioassay of lindane in mice. The incidence of hepatocellular carcinomas in low dose (80 ppm) males was significant when compared to pooled controls, but not in the high dose (160 ppm) males. The evidence indicates that lindane is carcinogenic to mice when administered orally, producing liver tumors. The IARC have classified lindane in Group 3; inadequate evidence for carcinogenicity in humans, limited evidence for carcinogenicity in animals and inadequate evidence for activity in short-term tests. EPA's Office of Pesticide Programs has stated, "Using the new Proposed Guidelines for Carcinogen Risk Assessment (cited above), the CAG has classified lindane as 'B2–C' (i.e., in between the lower half of the 'B' category of 'probable' and the 'C' category of 'possible' carcinogen classifications) based upon evidence that lindane gives rise to malignant liver tumors in two strains of mice, plus supportive evidence of pre-cancerous liver lesions in shorter term studies." This weight of evidence classification also included consideration that, on the one hand, at least one study was positive in both sexes and a lindane metabolite has been shown to be oncogenic, while, on the other hand, and leaning the classification toward class "C", lindane has not been shown to be mutagenic after extensive testing and

none of the oncogenicity studies showed a dose-response. Therefore, the weight of evidence appears to be closer to a Category C carcinogen than to Category B2 carcinogen.

Based upon the carcinogenic effects observed in the liver of mice fed lindane and using one of several models available, the NAS (*Drinking Water and Health*, 1977, Vol. I) estimated the possible carcinogenic risk of lifetime exposure to lindane for a person consuming two liters of water per day. EPA's CAG has also derived estimates of possible risk of daily exposure to lindane in drinking water. CAG also based the risk estimate on the liver carcinogenicity observed in mice. The NAS and CAG risk estimates are shown in Table 13.

The WHO proposed an ADI of 0.01 mg/kg bw and a guideline value in drinking water of 3 μg/l. The ADI was established by the Joint FAO/WHO Expert Committee on Food Additives and the guideline in drinking water was set at a level of one percent of the ADI.

EPA's MCL for lindane in drinking water, under the National Interim Primary Drinking Water Regulations, is 0.004 mg/l. This standard is based upon a NOAEL of 15 ppm (0.3 mg/kg), with an uncertainty factor of 500 and the assumption that 20 percent of the total intake is via drinking water. New data indicate that lindane is carcinogenic in the mouse and this data was not taken into account in the establishment of the interim MCL.

The available data do not permit definitive decisions on the oncogenic potential of lindane in the rat. The Office of Pesticide Programs is requiring that a rat oncognicity bioassay be performed (OPP, Sept. 30, 1985). Until definitive decision on the oncogenic potential of lindane is established, lindane will be classifed in EPA's Group C for the reasons outlined by the Office of Pesticide Programs, above. Lindane has been placed in Regulatory Category II and the RMCL has been set based upon the provisional AADI of 0.01 mg/l with an additional factor of 10, with 20 percent drinking water contribution factored in. The proposed RMCL is based upon a feeding study (Research Consulting., Ltd. 1983. OPP Support Document) in rats. Using 0.3 mg/kg/day (4 ppm) as the NOAEL, an uncertainty factor of 1000 based upon an animal study of short duration and consumption of 2 liters of water per day, a provisional AADI of 0.01 mg/l was calculated. An additional factor of 10 was applied because an order of magnitude uncertainty factor was determined to be sufficiently protective for this chemical. Alternatively, the RMCL could have been set based upon 1) the AADI approach using an additional uncertainty factor less than 10 due to the nature of the data, 2) the risk calculation approach (10^{-5} risk), or 3) the risk calculation approach (10^{-6} risk).

An RMCL and primary regulation will be proposed for lindane because of the potential adverse effects and occurrence in drinking water. Lindane has been classified as a possible carcinogen and the proposed RMCL of 0.0002 mg/l for lindane is based on a provisional AADI of 0.01 mg/l for non-carcinogenic effects and an additional factor of 10, assuming 20 percent contribution from drinking water.

Questions for Comment:

1. Is it appropriate to propose an AADI for lindane based on a shorter than lifetime feeding study in animals (Research Consulting Co. Ltd. 1983)?

2. In the background document on lindane, alternate studies (Fitzhugh, et al. 1950. The Chronic Toxicities of Technical Benzene Hexachloride and its Alpha, Beta and Gamma Isomers. J. Pharmacol. Expo. Ther. 100:59, and Rivett, et al. 1978. Effects of Feeding Lindane to Dogs for Periods of up to Two Years. Toxicology. 9:273) are cited in the consideration of an AADI. Comments are requested on their appropriateness in the derivation of an AADI.

3. Is it more appropriate to classify lindane in EPA's Group B2 or Group C? On what basis?

4. If lindane is classified in EPA's Group C, should the RMCL be based upon the AADI approach or the risk calculation approach? If the AADI approach is used, should an extra uncertainty factor of 10 be applied or some lesser value? If the risk approach is used should be RMCL be based upon the 10^{-5} or 10^{-6} risk level?

16. Methoxychlor

Methoxychlor [(2,2-bis (p-methoxyphenyl) 1,1,1-trichloroethane; CAS # 72-43-5; current MCL is 100 μg/1], a chemical closely related to DDT, has been used as an insecticide for approximately 40 years. Technical methoxychlor is a mixture containing 88 percent of the p,p'-isomer. In 1977, domestic consumption of methoxychlor was 10 million pounds. Methoxychlor has been widely used for home and garden applications, as well as on domestic animals, tree, and in waters. The p,p'-isomer is soluble in water to 0.26 mg/l at 25°C. The half life for methoxychlor in water is estimated to be 46 days and thus it is not considered to be persistent.

Analytical Methods. Analytical methods available for analyzing methoxychlor in drinking water include the solvent extraction-gas chromatography technique.

Human Exposure. In the FDA FY 79 total dietary studies for adults, methoxychlor was detected in 1 out of 10 dairy products sampled at 6 μg/kg. Methoxychlor was also detected in 1 out of 10 whole milk smples at a level of 2 μg/kg in the dietary study for infants. Residues of methoxychlor ranging from 2-6 μg/kg were reported in a whole milk sample, a sample of the dairy and other substitutes, and in a fruit and fruit juice sample from toddler studies. Compliance reports for FY 76 reveal that methoxychlor was detected in 1 percent of domestic food samples tested. In addition, methoxychlor levels in violation of the USDA maximum allowable level were detected in 0.2 percent of samples of calf tissues for 1982-1983.

The tolerance levels set by EPA's Office of Pesticide Programs for residues of methoxychlor in or on raw agricultural commodities are given below:

- One hundred parts per million in or on alfalfa, clover, cowpeas, grass for forage, peanuts and soybeans.
- Fourteen parts per million in or on various fruits and vegetables.
- Seven parts per million in or on sweet potatoes and yams from preharvest and postharvest application.
- Three parts per million in or on the fat of meat from cattle, goats, hogs, horses or sheep.
- Two parts per million in or on the following grains from storage-bin treatment: barley, corn, oats, rice, rye, sorghum grain and wheat.
- A 1.25 ppm in milk fat reflecting negligible residues in milk.
- One part per million in or on potatoes.
- One part per million inor on horseradish.

No data are availaable on levels of methoxychlor in ambient air.

Methoxychlor has not been detected during national drinking water monitoring surveys. Compliance monitoring has not reported methoxychlor in excess of the MCL. However, methoxychlor has been detected in drinking water in high use areas. One state study on the effects of forest runoff on the quality of water supply systems observed an ambient concentration of methoxychlor of 50 μg/l. In one county, 46 percent of the samples of rural water supplies contained detectable levels of methoxychlor (mean of 0.033 μg/l); in another, 64 percent of the samples were positive (mean of 0.023 μg/l).

Health Effects. Methoxychlor exhibits a wide range of toxicity when administered at high dose levels to animals. Central nervous system effects were observed in dogs, chronic nephritis and cystic tubular nephropathy in swine and rats, fatty changes in the livers of swine and marked testicular atrophy in rats and swine. Histopathologic changes in the kidneys, liver or reproductive organs were not observed at dietary levels below 1000 mg/kg.

One-day assessments for methoxychlor were based upon a study investigating the effects of methoxychlor following a single oral dose of 640 mg/kg in rats (Morgan and Hickenbottom, 1979. Relative Sensitivities of Various Biochemical, Toxicological and Pathological Techniques in Demonstrating Sublethal Lesions in the Rat Following Oral Administration of Low Levels of Methoxychlor. Toxicol. Appl. Pharmacol. 45:237). The effects observed were decreased lactate and glycogen phosphorylase and increased glucose-6-phosphatase. Using 640 mg/kg/day as the LOAEL, an uncertainty factor of 1000 based upon an animal study and consumption of 1 liter (child) or 2 liters of water (adult) per day, 1-day assessments of 6.4 mg/l for a 10 kg child and 22.4 mg/l for a 70 kg adult were calculated.

Ten-day assessment for methoxychlor were based upon a study (Stein, 1968. Comparative Methoxychlor Toxicity in Dogs, Swine, Rats, Monkeys and Man. Ind. Med. Surg. 37:540) in which volunteers were given methoxychlor at levels of 0.5, 1.0 or 2.0 mg/kg/day. No effects were reported for routine biochemical and histological examination of the organs. Using 2.0 mg/kg/day as a NOAEL, an uncertainty factor of 10 and consumption of 1 liter (child) or 2 liters of water (adult) per day, 10-day assessments of 2.0 mg/l for a 10 kg child and 7.0 mg/l for a 70 kg adult were calculated.

An AADI was calculated for methoxychlor based upon a feeding study in rats where male and female rats (FDA (unpublished), 1951; Lehman, 1965), fed diets containing 10, 25, 100, 500 or 2000 mg/kg/diet methoxychlor for 2 years. Growth retardation occurred at the highest dosage level in males, and at dosage levels of 200 mg/kg/diet and above for females. Using 5 mg/kg/day (100 mg/kg/diet) as the NOAEL, an uncertainty factor of 100 based upon an animal study and consumption of 2 liters of water per day, an AADI of 1.7 mg/l was calculated.

The evidence from studies with experimental animals and *in vitro* assays indicates that methoxychlor is not a carcinogen, mutagen or teratogen under the conditions of the experiments. A National Cancer Institute bioassay (NCI. 1978. Biassay of Methoxychlor for Possible Carcinogenicity. NCI–CG–TR–35) reported inconclusive results. Male and female rats were exposed to technical grade methoxychlor in the diet for 78 weeks. It was concluded by the investigators that methoxychlor was not carcinogenic under the conditions of the reported assay. Re-examination of the data by an independent pathologist indicated that methoxychlor was carcinogenic in the studies; however, recent reviews by EPA's CAG in 1984 of the NCI bioassay program recommended that the results be considered neither positive or negative, but inconclusive. Methoxychlor has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inconclusive results in animal tests.

Negative results were obtained from a number of mutagenicity studies in bacteria and yeast, from assays of methoxychlor induced DNA damage in DNA repair-deficient strains, from recessive lethal assays in *Drosophila melanogaster* and in assays of unscheduled DNA synthesis in mammalian cell cultures.

EPA's MCL for methoxychlor in drinking water, under the National Interim Primary Drinking Water Regulations, is 0.1 mg/l. This level was based upon human studies which identified a NOAEL of 2 mg/kg/day, with an uncertainty factor of 100 due to short-term human data (2 months) and 20 percent contribution from drinking water. The NAS (*Drinking Water and Health*, 1977. Vol. I) has calculated an ADI for methoxychlor of 0.1 mg/kg/day based on a 2-year study (Hodge, et al., 1952. Chronic Oral Toxicity Tests of Methoxychlor in Rats and Dogs. J. Pharmacol. Exp. Ther. 104:60) in rats, using a NOAEL of 10 mg/kg/day and an uncertainty factor of 100. The AADI is based upon a lower identified NOAEL in a newer study compared with the NAS' ADI.

The WHO has established an ADI for humans of 0 to 0.1 mg methoxychlor/kg bw (Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues, 1975). The basis of the ADI was not identified. The WHO has also recommended a guideline value (1984) of 30 μg/l for methoxychlor based upon drinking water as one percent of the ADI.

A detection odor threshold value of 4.7 mg/l in water for methoxhchlor is reported in the literature.

Methoxychlor has been shown to exhibit chronic toxic effects at high dose levels and has been detected in drinking water. The RMCL will be based upon non-carcinogenic effects; assuming 20 percent contribution from drinking water and based upon an AADI of 1.7 mg/l; and RMCL of 0.34 mg/l is proposed.

17. Monochlorobenzene

Monochlorobenzene (chlorobenzene CAS #108–90–7) is a solvent with a vapor pressure of 12.4 mm Hg at 25 °C. It is nearly insoluble in water. In 1981, 129,500 kkg of monochlorobenzene were produced in the U.S. Monochlorobenzene is used as a solvent in cold cleaning operations and pesticide manufacturing. These uses accounted for half of its production in 1978. Releases of monochlorobenzene to air from production and use processes in 1978 where estimated to be 79,500 kkg. Data are not available on releases to land and water. Quantities of monochlorobenzene entering surface waters are expected to volatilize to ambient air. Little informationis available on the fate of monochlorobenzene in the atmosphere.

Analytical Methods. Analytical methods available for analyzing monochlorobenzene in drinking water include the purge and trap-gas chromatography and the purge and trap-gas chromatography/mass spectrometry techniques.

Human Exposure. Insufficient data are available on levels of monochlorobenzene in foods to determine a daily dietary intake.

Ambient air monitoring data are available from over 800 site locations in 18 States. From median values of these data, the estimated rural/remote, urban/suburban and source dominated levels of monochlorobenzene in ambient air approximate 0.0, 1500 and 140 ng/m^3, respectively. Therefore, respiratory intake for the adult male is expected to vary from 0 to 32 μg/kg/day. Respiratory intake for formula-fed infants could vary between 0 and 22 μg/kg/day.

Drinking water monitoring data indicated that 99.9 percent of the public drinking water systems contain either no monochlorobenzene or levels less than 0.5 μg/l; 0.1 percent are estimated to have levels of monochlorobenzene in drinking water ranging from 0.5 to 5 μg/l. All exposure to monochlorobenzene in drinking water at levels above 0.5 μg/l is projected to come from ground water sources. Monochlorobenzene has been detected in drinking water in three States.

Monochlorobenzene has been identified at five hazardous waste sites designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of monochlorobenzene was not given for four sites; however, ground water migration was mentioned as a problem at two sites, one of which had a concentration in ground water of 100 mg/l.

Health Effects. Acute, high dose effects of monochlorobenzene include sedation, anesthesia and death due to respiratory failure. Chronic exposure to these compounds may result in blood dyscrasias and lung, liver and kidney damage. The principal target organs of monochlorobenzene are the central nervous system, liver and kidney.

No adequate dose-respones data are available from which to derive a 1-day assessment for either the 10 kg child or the 70 kg adult. It is recommended that, for this duration of exposure, the 10-day assessment be applied.

The 10-day assessment was derived from inhalation data in the teratology study in rats and rabbits (Hayes, et al., 1982. Monochlorobenzene inhalation teratology study in rats and rabbits. Unpublished report. Toxicology Research Laboratory. Dow Chemical Company. 115 pp.). Animals were exposed at 0, 75, 210 or 590 ppm, 6 hr/day on days 6–15 (rat) or days 6–18 (rabbit) or pregnancy. No toxicity, fetal or maternal, was observed in the rats at any dose. In the rabbit dams, increased relative and absolute liver weights were observed at the two higher doses. Using the NOAEL of 75 ppm (18 mg/kg/day), a 10-day assessment for the 10 kg child of 1.8 mg/l was derived. A comparable assessment for the 70 kg adult would be 6.3 mg/l.

The study selected for the derivation of the provisional AADI was a subchronic study in which rats and mice were administered monochlorobenzene five times weekly by gavage in corn oil at doses of 0, 60, 125, 250, 500 or 750 mg/kg (Battelle-Columbus, 1978c. Chlorobenzene. Subchronic Toxicity Study $B_6C_3F_1$ Mice. Unpublished report; Battelle-Columbus, 1978d. Chlorobenzene. Subchronic Toxicity Study—Fischer 344 Rats. Unpublished report). This study showed significantly increased liver/body weight ratios in mice of both sexes at 500 and 750 mg/kg, and a slight increase in males at 125 mg/kg. Both male and female rats showed an increase in liver/body weight ratios at 250 and 500 mg/kg. Mice and rats at the three highest doses all exhibited hepatic necrosis, nephrosis and lymphoid necrosis. A NOAEL of 125 mg/kg/day was identified from this study. Using this NOAEL, an uncertainty factor of 100 based upon an animal study with the NOAEL identified, and uncertainty factor of 10 to convert from subchronic to chronic exposure and consumption of 2 liters of water per day, a provisional AADI of 3.0 mg/l was determined.

Using the same NOAEL of 125 mg/kg/day and an uncertainty factor of 100 based upon an animal study identify a NOAEL and adjusting for exposure, a 10-day assessment of 30 mg/l for a 70 kg adult and 9 mg/l for a 10 kg child can be derived. These levels are also protective for 1-day exposures in the adult and child.

Monochlorobenzene has been shown to cause mutagenic effects in higher plants and certain microorganisms. Monochlorobenzene was tested for its carcinogenic potential in rats and mice in the NTP bioassay program (NTP, 1983. Draft NTP Technical Report of the Carcinogenicity Bioassay of Chlorobenzene (CAS #108–90–7) in F344/N Rats and $B_6C_3F_1$ Mice). The results of the study showed that monochlorobenzene administration increased the occurrence of neoplastic nodules of the liver in the high dose (120 mg/kg) male rats. Carcinogenic effects were not observed in female rats or mice of either sex. On the basis of these preliminary data, the NAS (*Drinking Water and Health*, 1983. Vol. V) derived an estimate of risk of daily exposure to monochlorobenzene in drinking water. This risk estimate is shown in Table 13.

EPA's ambient water quality criteria (U.S. EPA. 1980. Ambient Water Quality Criteria for Chlorinated Benzenes 440/5–80–028) for monochlorobenzene are 488 μg/l based upon toxicity data and 20 μg/l based upon organoleptic data. The level based upon toxicity data (488 μg/l) was calculated based upon a NOAEL from animals of 14.4 mg/kg/day and an uncertainty factor of 1000. The provisional AADI was based upon newer data than as used to derive the water quality criteria level. the WHO drinking water quality quideline for monochlorobenzene (1984) is 0.3 μg/l, based upon organoleptic considerations.

Monochlorobenzene has been classified in EPA's Group C, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon the preliminary data from the NTP study. Monochlorobenzene has been placed in Regulatory Category II and the RMCL has been set based upon the provisional AADI of 3.0 mg/l with an additional factor of 10, with 20 percent drinking water contribution factored in. The RMCL is proposed based upon chronic toxicity data because the bioassy data (NTP study) are preliminary and an inadequate basis for extrapolation. An additional factor of 10 was applied because an order of magnitude uncertainty factor was determined to be sufficiently protective for this chemical.

An RMCL and primary regulation will be proposed for monochlorobenzene because of the potential adverse effects and occurrence in drinking water. Monochlorobenzene has been classified an a possible carcinogen and the proposed RMCL of 0.06 mg/l for monochlorobenzene is based on a provisional AADI of 3.0 mg/l for non-carcinogenic effects and an additional factor of 10, assuming 20 percent contribution from drinking water.

Questions for Comment:

1. Should monochlorobenzene be classified in EPA's Group C?

2. What should be the basis for the RMCL for this compound?

3. The 10-day assessments, based upon a study done in rabbits, are lower than the Longer-term assessments or the AADI which were derived from studies performed with rats and mice. It is apparent that these species exhibit differing sensitivities to the chemical. That the rabbit were used for the 10-day assessment is in keeping with the philosophy of using information from the most sensitive species tested. However, data on the rabbit were not available for longer durations of exposure. Is it appropriate to use the rabbit data for the 10-day assessment or should data from the comparable study in the rat have been used? Should the Longer-term assessment and/or the AADI be modified to accommodate for the lack of data in the more sensitive species and, thus, perhaps, an inadequate margin of safety when attempting to identify a level of exposure for the human that would be protective?

18. Polychlorinated Biphenyls

Polychlorinated biphenyls (PCBs) are a class of colorless and stable chemicals. They contain a biphenyl nucleus with two or more substituent chlorine atoms. Technical PCBs are mixed isomers from 10 classes of chlorobiphenyls containing 209 possible isomers. In general, PCBs are insoluble in water and are soluble in many common organic solvents.

Prior to 1971, mixtures containing up to 68 percent chlorine were used in a number of applications, including plasticizers, heat transfer fluids, hydraulic fluids, compressor lubricants, wax extenders, waterproofing aids (in surface coatings), printing inks,

carbonless copy paper, as well as ingredients in lacquers, paints, varnishes and special adhesives. In 1974, PCBs were a major component of capacitors and of transformers and millions of pounds were manufactured. After 1976, the manufacture of PCBs was discontinued in the U.S.

Analytical Methods

Analytical methods available for analyzing PCBs in drinking water include the solvent extraction gas chromatography technique.

Human Exposure. The FDA estimated the total adult intake of PCBs to be 0.93 μg/day. The major sources are dairy products (0.37 μg/day); meat, fish, and poultry (0.52 μg/day); and fats and oils (0.03 μg/day). Trends in daily intake for the years 1977, 1978, and 1979 are 0.016, 0.027 and 0.014 μg/kg body weight, respectively.

No information was available on human intake of PCBs from ambient air.

National data on the level of PCBs in drinking water comes from the National Organics Monitoring Survey (NOMS) conducted in 1976–77. PCBs were found in 6 percent of finished ground water supplies at levels of 0.1 μg/l. PCBs were detected in approximately 2 percent of finished surface water systems; quantified levels were less than or equal to 1.4 μg/l. In a report published in 1978, one State indicated that PCBs were observed in 32 out of 163 ground water supplies sampled; concentrations as high as 1.27 μg/l were detected.

PCBs have been identified at ten hazardous waste sites designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of PCBs ranged from no level given for three sites, 4–20 μg/l in runoff, 11.7–200 μg/l in sediments, 127–444,000 μg/l in soil, 200μg/l in creek water, 7–175 μg/l in leachate, 60–215 pounds in an underground oil-water layer, to 26 μg/l in pond effluent.

Health Effects. Short and longer term exposure to PCBs in animals in a variety of physiological and morphological alterations to the liver including liver enlargement, fatty infiltration, centrilobular necrosis and effects on liver prophyrin metabolism. The major biochemical effects of PCBs are the inductive effect on hepatic mixed-function oxidase enzymes and modification of prophyrin metabolism. Short-term assessments or a provisional AADI have not been determined for PCBs.

PCBs have been studied for mutagenic effects using *Salmonella typhimurimum,* in the presence of a microsomal activation system. The results showed 4-chlorobiphenyl to be significantly mutagenic in this assay. A National Cancer Institute study (NCI, 1978. NCI Carcinogenesis Technical Report Series No. 38) examined the effects of PCBs ingested through the diet for 2 years. The results showed a high incidence of hepatocellular proliferative lesions as well as adenofibrosis; however, the incidence of hepatocellular adenomas and carcinomas was not found to be significant. In another study (Kimbrough, et al. 1975. Journal NCI. 55:1453), feeding of PCBs at a concentration of 100 mg/kg for 21 months resulted in neoplastic nodules and hepatocellular carcinomas. The IARC classified PCBs in Group 2B; inadequate evidence for carcinogenicity in humans, sufficient evidence for carcinogenicity in animals and inadequate evidence for activity in short-term tests. PCBs have been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assesment, based upon the positive results in studies in mice and rats.

EPA's CAG and the NAS have derived estimates of risk of daily exposure to PCBs based upon a long-term study (Kimbrough, et al. 1975 Journal NCI. 55:1453), in which rats were fed PCBs (Arochlor 1260) at a dose of 100 mg/kg body weight. The CAG and NAS risk estimates are shown in Table 13.

The available data suggests that PCBs (Arochlor 1260) have carcinogenic effects in animals. For this reason and because of the occurrence and potential occurrence of PCBs in drinking water, an RMCL and a primary regulation will be proposed. An RMCL of zero is proposed for PCBs as a class of compounds, based upon the carcinogenic effects noted for Arochlor 1260.

Questions for Comment:

1. Is there adequate evidence to base the RMCL for all PCBs upon carcinogenic effects?

2. PCBs include several chlorinated biphenyls and unknown contaminants. Variability in the health effects of several PCB isomers have also been reported. Is setting regulations for PCBs as a class of compounds appropriate? What alternative approach would be better?

19. Pentachlorophenol

Pentachlorophenol (PCB or penta) has been used as a herbicide, defoliant, insecticide, fungicide and wood preservative. Eighty percent of the pentachlorophenol produced is used in the treatment of wood. Pentachlorophenol is also used in termite prevention on farms. The only currently registered agricultural uses are seed treatment or seed crop uses. Pentachlorophenol is slightly soluble in water (18 mg/l at 25 °C). Pentachlorophenol has been used in wood products that come in contact with drinking water.

In July 1984, the Agency issues a notice of intent to cancel registrations for pesticides containing pentachlorophenol and/or its salts unless labeling was amended. EPA restricted wood preservative use to certified applicators; added protective measures to reduce exposure; prohibited application in homes and to most wood intended for indoor use or in contact with food, feed, or water; prohibited use of pentachlorophenol treated logs for construction of log homes; and required a limit on the hexadioxin contaminant. This Agency action has been challenged and administrative proceedings are underway. EPA has also issued a data call-in for non-chronic data such as mutagenicity, metabolism and air monitoring studies. In late 1984, the Agency also initiated actions to cancel virtually all registrations of pentachlorophenol for non-wood preservative uses.

Analytical Methods. Analytical methods available for analyzing pentachlorophenol in drinking water include the solvent extraction-gas chromatography technique.

Human Exposure. Although not detected in adult diet studies, pentachlorophenol was detected in 10 percent of oils and fat samples in the FDA infant diet study in 1979 at a concentration of 18 μg/kg. Additional data were obtained on the estimated total intake of pentachlorophenol for adults in 1974–1979 and for infants in 1975–1979. The average total intakes for adults, infants and toddlers over the years studied were 0.010, 0.005 and 0.009 μg/kg/day, respectively. The FDA toddler diet study of 1979 detected pentachlorophenol in 10 percent of the oils and fats samples at a concentration of 24 μg/kg.

Pentachlorophenol has been detected in rivers and streams (0.01–16 μg/l) and limited data show it may occur in drinking water from surface supplies. Pentachlorophenol was detected in the NSP in two surface water systems (1.3 and 12 μg/l). None of the 12 ground water systems examined for pentachlorophenol in the NSP contained levels in excess of the quantification limit of 1.0 μg/l.

Pentachlorophenol has been identified at one hazardous waste site designated

in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of pentachlorophenol was not given.

Health Effects. Pentachlorophenol is rapidly absorbed following oral exposure, with the major sites of tissue deposition being the livers, kidneys, brain, spleen and fat. It is rapidly excreted following a single dose, while during chronic exposure the biological half-life appears to be approximately 20 days. The major route of excretion is via the urine.

The major targets of pentachlorophenol toxicity are the liver, kidneys and central nervous system. Pentachlorophenol produces pigmentation, increases liver weight and induces hepatic enzymes in the liver. The major renal effects have been reported to be increased kidney weight and pigmentation, while effects on the central nervous system include capillary congestion and chromatolysis of the nerve cells. Pentachlorophenol is fetotoxic and has adverse effects on reproduction.

One-day assessment were calculated based on a study in rats (Nishimura, et al. 1982. Effects of Pentachlorophenol on the Levels of Hepatic Glycogen. Sangyo Isaku. 24(4):398–399) where a single oral dose of pentachlorophenol was shown to increase liver weights. Using a NOAEL of 10 mg/kg/day, an uncertainty factor of 100 and consumption of 1 liter (child) or 2 liters (adult) of water per day, a 1-day assessments of 1.0 mg/l for a 10 kg child and 3.5 mg/l for a 70 kg adult were calculated.

Ten-day assessments were calculated based on a NOAEL of 3 mg/kg/day for liver pathology in rats in a 90-day feeding study with pentachlorophenol (Johnson, et al. 1973. Chlorinated Dibenzodioxins and Pentachlorophenol. Environ. Health Perspec. Exp. 5:171–175) and for reproductive effects in a one-generation reproduction study in rats fed pentachlorophenol in the diet (Schwetz, et al. 1978. Results of 2-year Toxicity and Reproduction Studies on Pentachlorophenol in Rats. In: T.R. Rao, ed. Pentachlorophenol: Chemistry, Pharmacology and Environmental Toxicology. Plenum Press, NY pp. 301–309). Using an uncertainty factor of 100 and consumption of 1 liter (child) or 2 liters (adult) of water per day, 10-day assessments of 0.3 mg/l for a 10 kg child and 1.1 mg/l for a 70 kg adult were calculated.

An AADI was calculated for pentachlorophenol based upon a 24-month feeding study in which rats were fed doses of 0, 1, 3, 10 or 30 mg commercial pentachlorophenol/kg bw/day (Schwetz, B.A., J.F. Quast, P.A. Keeler, L.G. Humiston and R.J. Kociba, 1978. Results of 2-Year Toxicity and Reproduction Studies on Pentachlorophenol in Rats. In: K.R. Rao, ed. Pentachlorophenol: Chemistry, Pharmacology and Environmental Toxicology. Plenum Press. N.Y. pp. 301–309). At the highest dose level, increased serum glutamic pyruvic transaminase activity and pigmentation of the liver and kidney were observed in both males and females. At a dose of 10 mg/kg bw/day, pigmentation of the liver and kidney was observed in the females, but not in the males. An AADI of 1.1 mg/l was calculated from a NOAEL of 3 mg/kg/day, with an uncertainty factor of 100 based upon an animal study and consumption of 2 liters of water per day.

Commercial grades of pentachlorophenol used in toxicity studies with animals commonly contain the following nonphenolic contaminants: hexachloro-p-dioxin, heptachloro-p-dioxin, octachloro-p-dioxin, hexachlorodibenzofuran, heptachlorodibenzofuran, and octachlorodibenzofuran. These contaminants affect the toxicity of the pentachlorophenol being studied and would result in toxic effects being noted which could not be attributed to pentachlorophenol. 2,3,7,8-Tetrachlorodibenzo-p-dioxin was not detected in commercial pentachlorophenol used in the toxicity tests described above.

The NAS (*Drinking Water and Health*, 1977, Vol. 1) has calculated an ADI of 0.021 mg/l based on a 90-day feeding study in rats (Johnson, R.L., P.J. Gehring, R.J. Kociba and B.A. Schwetz, 1973. Chlorinated Dibenzodioxins and Pentachlorophenol. Environ. Health Persper. Exp. Issue No. 5, Sept. 1973, pp. 171–175). This value was determined before the results of the 24-month rats study which is more appropriate for an AADI calculation, due to the length of the study.

Pentachlorophenol has not been shown to be mutagenic in *Salmonella typhimurium, Escherichia coli* or *Serratia marcescens*. Two oral carcinogenicity studies have been carried out on pentachlorophenol. There were no significant differences in tumor response between treated and control animals in either of these studies. The National Toxicology Program is currently testing pentachlorophenol for carcinogenic activity. No data from these studies are currently available. The IARC has classified pentachlorophenol in Group 3; inadequate evidence for carcinogenicity in humans, inadequate evidence for carcinogenicity in animals and inadequate evidence for activity in short-term tests. Pentachlorophenol has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data in animal studies.

The EPA ambient water quality criterion for Pentachlorophenol (U.S. EPA. 1980. Ambient Water Quality Criteria for pentachlorophenol. EPA 440/5–80–065) is either 1.01 mg/l based on toxicity data or 0.03 mg/l based on the organoleptic properties of pentachlorophenol. The 1.01 mg/l value is based on the same study used for the AADI calculation and also considers bioconcentration by fish. In an EPA Position Document 4 on Wood Preservative Pesticides, the Agency regulatory position to restrict usage of pentachlorophenol considered, with respect to health risk, teratogenicity and fetotoxicity of pentachlorophenol and oncogenicity of its hexachlorodibenzo-p-dioxin (HxCDD) and hexachlorobenzene contaminants.

Odor thresholds of 857 μg/l at 30 °C and 1600 μg/l at 20–22 °C and a taste threshold of 30 μg/l have been reported in the literature for pentachlorophenol. The WHO guideline for pentachlorophenol (1984) is 10 μg/l. This value is based upon an ADI of 3 μg/kg body weight with 10 percent of the ADI attributable to drinking water. The ADI was based upon an uncertainty factor of 1000 applied to unspecified animal data.

Although commercial pentachlorophenol contains residues of hexa- and octachlorodioxin, the RMCL is based upon the parent pentachlorophenol. This is because data indicates that the mobility of the dioxin contaminants is often less than the mobility of the parent compound and thus the parent compound would be the chemical of concern in drinking water. The potential exposure to the dioxin contaminant will be dealt with separately (see section on 2,3,7-tetrachlorodibenzo-p-dioxin).

Exposure to pentachlorophenol at sufficient levels results in effects on the liver and kidney. Since pentachlorophenol has been detected in drinking water and is likely to be occurring in drinking water, an RMCL and primary regulation will be proposed. An RMCL of 0.2 mg/l is proposed based upon an AADI of 1 mg/l and an assumed drinking water contribution of 20 percent.

Questions for Comment:

1. Are additional data available on exposure through food, air and other sources for pentachlorophenol?

2. Is there adequate toxicological evidence that the presence of detected non-phenolic contaminants in commercial pentachlorophenol would affect the AADI?

20. Styrene

Styrene (vinyl benzene or ethenyl benzene; CAS # 100-42-5) is slightly soluble in water (0.32 mg/l) and soluble in many organic solvents. In 1982, the total U.S. production of styrene equaled 5,942,037 pounds. Styrene is used extensively for the manufacture of plastics, including polystyrene, rubber modified impact polystyrene, acrylonitrile-butadiene-styrene (ABS), and styrene-acrylonitrile copolymer (SAN). It is also used in the manufacture of synthetic rubber, resins, and insulators. Some resins manufactured from styrene are used in the treatment of potable water.

Analytical Method. Analytical methods available for analyzing styrene in drinking water include the purge and trap-gas chromatography technique.

Human Exposure. No information is available on the occurrence of styrene in food. Low level contamination of some foods is expected because polymers and resins of styrene used in packaging commonly contain a detectable level of the monomer.

Data on exposure to styrene through inhalation of ambient air are limited. Styrene has been detected in ambient air in source dominated areas at approximately 2.3 $\mu g/m^3$. This level could lead to a respiratory intake for adults of approximately 52 μg/day.

Nearly 1000 drinking water samples from ground water and 100 surface water supplies have been tested in national monitoring surveys to determine the presence or absence of styrene. Styrene was not detected in any of these samples.

Styrene has been identified at one hazardous waste site designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of styrene was not given.

Health Effects. Styrene is readily absorbed from the gastrointestinal tract and distributed throughout the body, accumulating in adipose tissue. Styrene is metabolized to styrene oxide, a highly reactive intermediate. The acute toxicity of styrene is relatively low, with reduced weight gain, increased kidney and liver weights and lung congestion exhibited following non-lethal exposures. Repeated inhalation exposures at very high dose levels in animals have been reported to result in alterations in hepatic enzyme activity and biochemical changes in the brain.

One-day assessments are based upon a study (Srivastava, et al. 1982. Hepatic Effects of Orally Administered styrene in Rats. J. Appl. Toxicol. 2(4)219-222) in which the NOAEL for increased sensitivity of dopamine receptors in the brain was determined to be 270 mg/kg/day. An uncertainty factor of 100 was applied and the consumption of drinking water was based upon 2 liters/day for the adult and 1 liter/day for the 10 kg child. The one-day number is 94.5 mg/l for the adult and 27 mg/l for the 10 kg child.

Ten-day assessments are based upon minor hepatotoxicity in rats (Agrawal, et al. 1982. Effects of Styrene on Dopamine Receptors. Bull. Environ. Contam. Toxicol. 29(4):400-403). A NOAEL of 200 mg/kg day was determined, with an uncertainty factor of 100 and consumption of 1 liter (child) or 2 liters (adult) of water per day. Ten-day numbers of 70 mg/l for the adult and 20 mg/l for the 10 kg child were determined.

A provisional AADI was calculated from a study where beagle dogs were given styrene in a peanut oil suspension by gavage 7 days/wk for 560 days (Quast, J.F., R.P. Kalnins, K.J. Olson, et al., 1978. Results of a toxicity study in dogs and teratogenicity studies in rabbits and rats administered monomeric styrene. Tox. Appl. Pharm. 45:293-294). Dose levels were 200, 400 or 600 mg/kg bw/day. The controls received peanut oil only. At the two higher dose levels, minimal histopathogolic effects were noted in the liver (increased iron deposits within the reticuloendothelial cells) as well as hematologic effects that included increased Heinz bodies in erythrocytes and a decreased packed cell volume. At the lowest dose level (200 mg/kg/day), these effects were not noted. Using 200 mg/kg/day as a NOAEL in both species and an uncertainty factor of 1000 based on an animal study of less than lifetime exposure and consumption of 2 liters of water per day, a provisional AADI of 7 mg/l was determined.

Styrene has not been shown to be mutagenic in *Salmonella typhimurium* in the absence of metabolic activation, while positive results have been obtained in yeast, fruit flies and cultured mammalian cells with metabolic activation. Styrene produced positive results in cultured mammalian cells, isolated human lymphocytes and when tested *in vivo* in rats and mice.

The NAS (*Drinking Water and Health*, 1977. Vol. I) has calculated an ADI of 0.133 mg/kg/day based upon a study in rats (Wolf, M.A., et al. 1956. Toxicological Studies of Certain Alkylated Benzenes and Benzene. Arch. Ind. Health. 14:387-389). Using a NOAEL of 0.133 mg/kg/day, with an uncertainty factor of 1000 and the assumption that 20 percent of total intake is via drinking water, a value of 0.9 mg/l was determined.

Styrene has been tested for carcinogenicity in several animal studies. In one study (Ponomarkov, V.F. and Tomatis, L., 1980. Effects of Long Term Oral Administration of Styrene to Mice and Rats. Scand. J. Work Environ. Health. 4 (Suppl. 2)127-135), an increased incidence of lung tumors was found in one strain of mice, but this dose resulted in excessive early mortality. Elevated tumor incidences were not observed in another strain of mice or rats. In the National Cancer Institute bioassay of styrene, a statistically significant increase in alveolar/bronchiolar adenomas and carcinomas was seen in male and female rats at a dose of 300 mg/kg/day (NTP, NCI No. 1985, 1979). In an inhalation study (Jersey, G.M., et al. 1978. Two year Chronic Inhalation Toxicity and Carcinogenicity Study on Monomeric Styrene in Rats. Dow Chemical Study for MCA. Dec. 6, 1978), the incidence of leukemia/lymphosarcomas was slightly elevated in female rats. The IARC has classified styrene in Group 3: inadequate evidence for carcinogenicity in humans, limited evidence for carcinogenicity in animals and sufficient evidence for activity in short-term tests.

Styrene has been classified in EPA's Group C, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment based upon several positive animal studies which are limited due to poor survival of the animals. Styrene has been placed in Regulatory Category II and the RMCL is proposed based upon the provisional AADI of 7.0 mg/l with an additional factor of 10, with 20 percent drinking water contribution factored in. The RMCL is based upon chronic toxicity data because the bioassay data are very limited and inadequate for extrapolation purposes. An additional factor of 10 was conservatively applied based upon the equivocal evidence of carcinogenicity.

The odor threshold for styrene is between 10 and 60 ppm while the taste threshold is between 0.005 and 0.773 mg/l.

Exposure to styrene at high dose levels results in adverse health effects in animals. Because styrene is likely to be occurring in drinking water, EPA will propose an RMCL and primary regulation. An RMCL of 0.14 mg/l is proposed, based upon an AADI of 7 mg/

l with an additional factor of 10 and 20 percent drinking water contribution.

Question for Comment:

1. Should styrene be classified in EPA's Group C? What should be the basis for the RMCL for this compound?

21. Toluene

Toluene [methyl benzene; CAS #108-88-3] is an aromatic solvent. It is slightly soluble in water (534.8 mg/l) and is soluble in alcohol, benzene, ether, acetone, and other organic solvents. Much of the toluene produced is blended directly into aviation gasoline. Toluene also is used as a starting material in the production of benzene and other chemicals, and is used as a solvent for paints, coatings, gums, oils, and resins.

Analytical Method. Analytical methods available for analyzing toluene in drinking water include the purge and trap-gas chromatography technique.

Human Exposure. No information was available on the intake of toluene from food.

Data compiled for EPA's Office of Air Quality Planning and Standards indicate that the mean ambient air levels of toluene are 0.3 $\mu g/m^3$ for rural/remote areas, 2.6 $\mu g/m^3$ for urban/suburban areas, and 23 $\mu g/m^3$ for source dominated areas. Using the value of 3.6 $\mu g/m^3$, the mean respiratory intake of toluene for adults is calculated to be 83 μg/day.

In the CWSS, toluene was measured in two ground water systems, at concentrations of 0.505 and 0.56 $\mu g/l$. Three surface water supplies had measurable concentrations of toluene—0.52, 0.72 and 1.62 $\mu g/l$. Toluene was detected in six randomly selected systems tested during the GWSS. Levels ranged from 0.5–2.9 $\mu g/l$.

In the NSP, approximately 20 percent of the surface water supplies sampled contained detectable levels of toluene in finished water. Measured concentrations ranged from 0.1 to 1.4 $\mu g/l$, with a mean of 0.295 $\mu g/l$. A level of 0.1 $\mu g/l$ was measured in the one ground water system in which toluene was detected.

State agencies have also detected toluene in drinking water. Levels as high as 2,500 $\mu g/l$ have been reported.

Health Effects. Acute exposure to high levels of toluene in animals results in central nervous system depression and effects on the lungs, liver and kidney. Toxic effects following chronic exposure are similar to those seen following acute exposure, predominantly on the kidneys and lungs (if via inhalation).

No adequate dose-response data developed via the oral route of exposure exist from which to derive 1-day assessments. Thus, their derivation was based upon a 100 ppm (377 mg/m^3) NOAEL identified in humans following single inhalation exposures of up to 8 hours (von Oettingen, et al. 1942a. The Toxicity and Potential Dangers of Toluene, with Special Reference to its Maximal Permissible Concentration. U.S. Public Health Service Pub. Hlth. Bull. No. 279. 50 pp; von Oettingen, et al. 1942b. The Toxicity and Potential Dangers of Toluene—Preliminary report. J.A.M.A. 118:579–584; Carpenter, et al. 1944. Studies on the Inhalation of 1,3-Butadiene; with a Comparison of its Narcotic Effect with Benzol, Toluol and Styrene, with a Note on the Elimination of Styrene by the Human. J. Ind. Hyg. Toxicol. 26:69–78; Ogata, et al. 1970. Urinary Excretion of Hippuric Acid and m- or p-Methylhippuric acid in the Urine of Persons Exposed to Vapors of Toluene and m- or p-Xylene as a Test of Exposure. Brit. J. Ind. Med. 27(1): 43–40). A total absorbed dose of 18 mg/kg was determined, assuming a human respiratory inhalation volume of 20 m^3/day and an absorption efficiency of 50 percent for a 70 kg adult. From this total absorbed dose, a 1-day number of 18 mg/l was derived for the 10 kg child, assuming consumption of 1 liter of water per day. A 1-day number of 63 mg/l was derived for the 70 kg adult, assuming consumption of 2 liters of water per day, applying an uncertainty factor of 10, appropriate for use with adequate human data.

Because of the lack of appropriate exposure duration data, the 10-day assessments were derived from the 1-day assessments by dividing each 1-day number by 3 to give estimated 10-day values. The use of a 3-fold uncertainty factor, rather than the more usual 10-fold factor, is substantiated by the nature of the kinetic and toxic properties of the compound, i.e., rapid uptake and excretion and little bio-accumulation potential. The resulting 10-day number for the 10 kg child is 6 mg/l and for the 70 kg adult, 21 mg/l.

An AADI has been determined for toluene based upon a laboratory study in which rats were exposed to toluene via inhalation at 0, 113, 337 or 1130 mg/m^3 for 6 hours/day, 5 days/week for up to 2 years (C.I.I.T., 1980. Unpublished. A Twenty-four Month Inhalation Toxicology Study in Fisher-344 Rats Exposed to Atmospheric Toluene). No dose-related adverse effects were identified from this study and a NOAEL of 1130 mg/m^3 was identified. Using this NOAEL, an uncertainty factor of 100 based upon an animal study and assuming 50 percent pulmonary absorption, an AADI of 10.1 mg/l was determined.

Toluene has not been shown to be mutagenic in the Ames *Salmonella typhimurium* assay, with or without rat liver S-9 homogenate, and has been shown to be ineffective in increasing the reversion of an *E. coli* strain to tryptophan-independence.

Limited data are available on the carcinogenic effects of toluene. Only one long-term bioassay of toluene has been conducted; this study (C.I.I.T., 1980. Unpublished) concluded that toluene is not carcinogenic following inhalation in rats. The National Toxicology Program is conducting 2-year carcinogenicity bioassays on toluene in which the compound is being administered by inhalation and gavage to rats and mice. Toluene has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon negative results in an inhalation study and inadequate data through ingestion exposure.

EPA's ambient water quality criterion (U.S. EPA. 1980. Ambient Water Quality Criteria for Toluene. 440/5–80–075) for toluene is 14.3 mg/l based upon a 6-month oral study in rats (Wolf, et al. 1956. Toxicological studies of Certain Alkylated Benzenes and Benzene. Arch. Ind. Health. 14:387). The study used to derive the AADI is a lifetime study and was thus determined to be more appropriate for the derivation of the AADI than the 6-month study described above.

The odor threshold for toluene in drinking water is 1 mg/l.

Exposure to toluene at high dose levels results in central nervous system depression and other systemic effects; it has occurred in many drinking water supplies. Thus, a primary regulation will be proposed. The RMCL is proposed at 2.0 mg/l based upon an AADI of 10.1 mg/l for non-carcinogenic effects assuming 20 percent contribution from drinking water.

22. Toxaphene

Toxaphene (a mixture of C_{10} chlorinated camphenes with an approximate overall empirical formula of $C_{10}H_{10}Cl_8$; current MCL is 5 $\mu g/l$) is a persistent, broad spectrum insecticide. This product was used extensively on food and fiber crops for many years, but current registered uses are limited.

The solubility of toxaphene in water is approximately 0.4 mg/l. The EPA Toxaphene Work Group reported that toxaphene is highly persistent and accumulates in the environment.

Analytical Methods. Analytical methods available for analyzing toxaphene in drinking water include the

solvent extraction-gas chromatography technique.

Human Exposure. In FDA's compliance program report for FY 77 on pesticides and metals, toxaphene was detected in 3.3 percent of samples tested. In the FY 79 total dietary study, the FDA detected toxaphene levels ranging from 10 to 56 μg/kg in 10 percent of the garden fruits included in the dietary study for adults. Toxaphene was detected in 30 percent of the oils and fat samples for infants; concentrations ranged from 40 to 173 μg/kg. Residues of toxaphene ranging from 30 to 77 μg/kg were also reported in 10 percent of the vegetable samples and 60 percent of the oils and fat samples for toddlers.

Recent USDA activity (1982–83) failed to detect toxaphene residues in animal meat products.

Ambient air studies conducted between 1970–1978 reported maximum toxaphene levels as high as 8.7 $\mu g/m^3$. However, because of substantially reduced used rates since these studies, actual levels at this time are probably considerably lower.

Toxaphene has been detected in streams and rivers and in drinking water in two States and in twenty-seven systems tested by EPA. None of the surface or ground water systems analyzed during the RWS contained detectable levels of toxaphene. Compliance data from the National Interim Primary Drinking Water Regulation did not report toxaphene in excess of the MCL.

Health Effects. Acute exposure to toxaphene resuts in a variety of central nervous system effects, including salivation, hyper excitablity, behavioral changes and convulsions. The kidney, liver and testes are also affected by acute exposure to toxasphene. The critical target organ in chronic or subchronic exposure is the liver. One-day assessments were calculated based upon kidney and liver pathology as the critical endpoints. Using a LOAEL of 4 mg/kg/day, an uncertainty factor of 100 and consumption of one liter (child) or two liters (adult) of water per day, 1-day numbers of 0.5 mg/l for the child and 1.75 mg/i for the adult were calculated (Lackey, R.W. 1949. Observations on the Acute and Chronic Toxicity of Toxaphene in the Dog, J. Industrial Hygiene Toxicology. 31:117–129).

Ten-day numbers were based on the significant results of the Lackey (1949) study. Minimal kidney and liver pathology were reported in dogs exposed to toxaphene at 4 mg/kg bw/day for up to 44 days. These effects were not observed at higher doses in other species. It is uncertain if these effects occur within 10 days of exposure. Occasional convulsions were also noted at this level. Using the LOAEL of 4 mg/kg/day, the ten-day health advisory is 0.08 mg/l for a 10 kg child and 0.28 mg/l for a 70 kg adult, using an uncertainty factor or 500 and 2000, respectively.

The NAS (*Drinking Water and Health*, 1977, Vol. I) has calculated an ADI of 0.00123 mg/kg/day for toxaphene. This was based upon a 2-year rat study in which 1.25 mg/kg/day was selected as the NOAEL and an uncertainty factor of 1000.

Toxaphene has been shown to be mutagenmic in the *Salmonella* minrosomal reverse mutation assay, with mutagenicity decreased by the addtion of active function oxidases. The National Cancer Institute carried out a study (NCI. 1979. Bioassay of Toxaphene for Possible Carcinogenicity; NCI Carinogenesis Technical Report Series No. 37, DHEW Publication No. (NIH) 79–832) on the carcinogenicity of toxaphene in which male and female mice and rats were fed various doses of toxaphene added to the diet as an acetone solution, 2 percent corn oil. It was concluded that under the conditions of the bioassay, toxaphene was carcinogenic in male and female mice, causing incresed incidences of hepatocellular carcinomas in a dose related manner. The results also suggested that toxaphene was carcinogenic for the thyroid of male and female rats. In a separate study, with male and female mice (NCI, 1979. DHEW 79–832), increased incidences of hepatocelluar carcinoma in male mice were observed after 18 months of toxaphene ingestion in the diet. The IARC has classified toxaphene in Group 2; inadequate evidence for carcinogencity in humans and adequate evidence for carcinogenicity in animals. Toxaphene has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon the positive results in studies in rats and mice.

EPA's CAG have derived estimates of risk of daily exposure to toxaphene in drinking water based upon the incidence of hepatocellular carcinoma from an ingestion study in mice. Table 13 summarizes the CAG risk estimate.

EPA's MCL for toxaphene in drinking water, under the National Interim Primary Drinking Water Regulations, is 0.005 mg/l. This standard is based on the reported organoleptic effects of toxaphene at concentrations greater than 5 μg/l (Sigworth, E.A. 1965. Indentifiation and Removal of Herbicides and Pesticides. J.Am. Water Works Assoc. 57:1016).

EPA's ambient water quality criteria for human health, considering ingestion of contaminated water and aquatic organisms is suggested as concentration levels of 7.1 ng/l, 0.71 ng/l and 0.071 ng/l equivalent to calculated excess cancer risks of 10^{-5}, 10^{-6}, and 10^{-7}, respectively.

Toxaphene has been reported to have an organoleptic threshold of 0.14 mg/l and the WHO has not determined a guideline for toxaphene in drinking water.

The available data indicates that toxaphene is a potent carcinogen in animals. For this reason and because there is some occurrence in drinking water, an RMCL and a primary drinking water regulation will be proposed. The RMCL will be based upon carcinogenic effects and an RMCL of zero is proposed.

23. 2,4,5-TP

2,4,5-TP [2-(2,4,5,-Trichlorophenoxy) propionic acid or silvex; CAS #93–72–1; current MCL is 10 μg/l] is a herbicide that has been used for weed and brush control on rangeland and rights of way, pastures, commercial or ornamental turf, home weed control and weed control in and along canals and other waterways.

2,4,5,-TP is soluble in water (140 mg/l at 25 °C). The environmental persistence of 2,4,5-TP is expected to be relatively short. Phenoxy acid herbicides undergo photolysis and bacterial degradation.

In 1979, EPA issued an emergency suspension order covering the use of 2,4,5-TP for weed and brush control in forests, rights of way, pastures, irrigation canals, and other waterways, turfs and homes. The suspension was never lifted, and all registrations for herbicides containing 2,4,5-TP are now canceled. While there is still limited use of existing stocks of certain 2,4,5-TP products (non-suspended uses only), the existing stocks period has expired for most products.

Analytical Methods. Analytical methods available for analyzing 2,4,5-TP in drinking water include the derivatization-gas chromatography technique.

Human Exposure. No comprehensive data are available on the levels of 2,4,5-TP in the U.S. food supply. Data on levels of 2,4,5-TP on apples in 1975 indicate the presence of residues in unwashed fruit of 97 μg/kg initially, decreasing to 36 μg/kg after 4 months of storage.

No data are available on levels of 2,4,5-TP in air.

2,4,5-TP has been found in drinking water in three States. Of eight surface systems sampled in the NORS, one large system was found to contain 0.02 μg/l 2,4,5-TP. In the NSP, 2,4,5-TP was not detected in any of the 105 surface water

systems sampled. None of the 21 surface water systems sampled during the RWS contained 2,4,5-TP in excess of the minimum quantification limit of 0.1 μg/l.

Concentrations of 2,4,5-TP ranging from 0.03 to 0.08 μg/l were found in a USGS survey of finished drinking water collected from 15 surface water systems in Florida.

National compliance reports show that one medium-sized surface system violated the MCL for 2,4,5-TP.

Finished drinking water samples from 3 out of 127 water supplies sampled in Florida contained 2,4,5-TP in the range of 0.04 to 0.06 μg/l. A USGS survey of ground water supplies in Florida also detected 2,4,5-TP at levels ranging from 0.04 μg/l to 0.30 μg/l.

2,4,5-TP has been found in hazardous waste and in waste water. The compound is mobile and is widely used.

Health Effects. 2,4,5-TP is contaminated to varying extents with 2,3,7,8-TCDD, a highly toxic polychlorinated dibenzo-p-dioxin. Substantial differences in the toxicity of 2,4,5-TP have been reported, probably based upon the degree of contamination of the compound.

Single, oral exposure to 2,4,5-TP at high doses causes a variety of physiological and biochemical effects including depression, posterior quarter muscle weakness, irritation of the stomach and minor liver and kidney damage in mammals. Subchronic exposure to 2,4,5-TP in animals has produced histopathologic changes in the liver and kidney, while chronic studies have noted adverse effects such as mild degeneration and necrosis of hepatocytes accompanied by elevation of SGOT and SGPT.

The available data are inadequate to estimate a 1-day assessment for 2,4,5-TP. Two unpublished studies by Dow Chemical (1982, 1983) that described the toxicity of 2,4,5-TP to rats and dogs were examined. No effects were reported in dogs administered 2 mg/kg/day 2,4,5-TP in the diet for 89 days. Only one dose level was employed in this study, and the available description of this unpublished work provided no details on the extensiveness of pathologic examination. In a companion study, rats administered 5 mg/kg/day of the sodium salt of PGBE ester of 2,4,5-TP for 90 days had an increase in relative weight of the liver and kidney with "histopathologic changes" in both.

Of these two studies, the study in the dog that identified a NOAEL of 2 mg/kg/day was used to calculate a 10-day assessment. Using the NOAEL of 2 mg/kg/day, an uncertainty factor of 100 based upon an animal study and consumption of 1 liter (child) of 2 liters (adult) of water per day, 10-day numbers of 0.2 mg/l and 0.7 mg/l were determined for the child and adult, respectively.

The NAS (*Drinking Water and Health*, 1977. Vol. I) has calculated an ADI for 2,4,5-TP based upon a two-year feeding study (Mullison, 1966. South Weed Conf. Proc. 19th Annual Meeting, Jacksonville, Florida, pages 420–435) in dogs in which 0.75 mg/kg/day was selected as the NOAEL. Using this NOAEL and an uncertainty factor of 1000, the NAS calculated an ADI of 0.0075 mg/kg/day.

The AADI will be determined based upon the same study used by the NAS to calculate the ADI (Mullison, 1966. South Week Conf. Proc. 19th Annual Meeting, Jacksonville, Florida, pp. 420–435). Using 0.75 mg/kg/day as the NOAEL, an uncertainty factor of 100 and consumption of 2 liters of water per day, an AADI of 0.26 mg/l has been determined.

A mutagenicity assay (Anderson, et al., 1972. J. Agric. Food Chem. 20(3):649) on 2,4,5-TP found that the compound did not cause point mutations in histidine-requiring mutants of *Salmonella typhimurium*. Limited data are available on the potential carcinogenicity of 2,4,5-TP. In one study (Innes, 1969. J. Natl. Cancer Inst. 42:1101), chronic oral exposure to 2,4,5-TP did not significantly increase the incidence of tumors at any site in mice exposed for 80–81 weeks, while another study (Gehring and Besto, 1978. Ecol. Bull. Stockholm. 27:122) also showed no increase in tumor incidence in rats or dogs exposed to 2,4,5-TP for 2 years. However, these studies did not employ the recent NCI bioassay procedure recommending the use of the maximum tolerated dose and half of the maximum tolerated dose and thus it is difficult to reach a conclusion on the carcinogenicity of the compound. 2,4,5-TP has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data from animal studies.

EPA's MCL for 2,4,5-TP in drinking water, under the National Interim Primary Drinking Water Regulations, is 0.01 mg/l. This standard is based upon a NOAEL of 0.9 mg/kg/day, with an uncertainty factor of 500 and the assumption that 20 percent of the total intake is via drinking water.

Exposure to 2,4,5,-TP at high dose levels results in a variety of chronic adverse health effects. Because this contaminant also has been detected in several drinking water systems, an RMCL and a primary regulation will be proposed. An RMCL of 0.052 mg/l is proposed based upon the AADI (0.26 mg/l) with 20 percent drinking water contribution.

24. Xylene

For the purposes of this proposal, xylene is considered to be the mixture (CAS # 1330–20–7) of three isomers (ortho-, CAS # 95–47–6; meta-, CAS # 108–38–3; and para-, CAS # 2106–42–3). Xylene isomers are slightly soluble in water and are soluble in alcohol, ether and many other organic liquids.

Xylene is used in aviation and automobile gasoline, protective coatings, in the synthesis of many organic chemicals, pharmaceuticals and vitamins, and as solvents for many preparations, including pesticides.

Analytical Methods. Analytical methods available for analyzing xylene in drinking water include the purge and trap-gas chromatography technique.

Human Exposure. No information was available on the human intake of xylene from food. The median level of o-xylene in ambient air reportedly ranges from 0.4 $\mu g/m^3$ in rural and remote areas to 3 $\mu g/m^3$ in source dominated areas. Median levels of m-and p-xylene (combined) range from 0.4 $\mu g/m^3$ to 73 $\mu g/m^3$ in source dominated areas. Based on these data, estimated maximum daily intake for adults in rural and source dominated areas, respectively, would approach 8 μg/day and 1.7 μg/day for all isomers (combined).

The results of the GWSS indicated that approximately 3 percent of the ground water systems contained detectable levels of xylene while the CWSS indicated that xylene was in 6 percent of the surface water supplies. The maximum detected level of contamination reported in federal and state surveys was 750 μg/l in ground water and 5.2 μg/l in surface water supplies.

Health Effects. The principal toxic effects of xylene are central nervous system disturbances, such as changes in numerative ability reaction time, short-term memory and electroencephalographic patterns. Xylene also affects the liver at very high concentrations. A 1-day number was calculated for xylene based upon an inhalation study in human volunteers (Gamberale, et al. 1978. Exposure to Xylene and Ethylbenzene. III. Effects on Central Nervous Functions. Scan. J. Work Environ. Health. 4:204). In this study, a NOAEL was determined at an inhalation concentration of 1300 mg/m^3 as for approximately one hour. Using 1300 mg/m^3 the NOAEL for a 1-day exposure, an uncertainty factor of 10 and consumption of 1 liter (child) or 2 liters of water (adult) per day, 1-day

numbers of 12 mg/l for a 10 kg child and 42 mg/l for a 70 kg adult were calculated.

Insufficient ingestion toxicological data are available to calculate 10-day numbers. However, 10-day numbers were calculated based upon a study (Carpenter, et al. 1975. Petroleum Hydrocarbon Toxicity Studies. V. Animal and Human Response to Vapors of Mixed Xylenes. Toxicol. Appl. Pharmacol. 33:543) in rats exposed by inhalation to mixed xylene at 2000 mg/m^3 for 6 hours/day (5 days/week) for up to 13 weeks. No significant effects on blood chemistry or tissue histology were reported as a result of the xylene exposure. Using 200 mg/m^3 as a NOAEL, an uncertainty factor of 100, and consumption of 1 liter (child) or 2 liters (adult) of water per day, 10-day numbers of 7.8 mg/l for a 10 kg child and 27 mg/l for a 70 kg adult were calculated.

A provisional AADI for xylene is based on an inhalation study (Jenkins, et al. 1970. Long-term Inhalation Studies on Benzene Toluene, o-Xylene and Cumene on Experimental Animals. Toxicol. Appl. Pharmacol. 16:818) in rats, guinea pigs, monkeys and dogs. In this study, animals were exposed at a dose level of 377 mg/m^3 continuously for 90 days. No statistically significant effects were observed with respect to body weight, hematology and histopathological examination of treated animals. Using 337 mg/m^3 as the NOAEL, an uncertainty factor of 1000 based upon an animal study with few animals per dose level, and consumption of 2 liters of water per day, a provisional AADI of 2.2 mg/l was calculated.

The estimated concentration for detection by taste and odor in surface water is 0.3 to 1.0 mg/l (Middleton, et al. 1958. J. Am. Water Works Assoc. 50:21).

Little data are available on the carcinogenicity of xylene. One study examined the dermal effects of xylene and concluded that xylene was not a skin tumorigen. A long-term carcinogenicity bioassay is presently being conducted by the National Toxicology Program. Mice and rats have been treated, but data from this study are not yet available. Xylene has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate data from animal studies.

Exposure to xylene at high dose levels has been shown to result in chronic toxic effects. For this reason and because there has been significant occurrence of this contaminant in water, an RMCL and a primary regulation will be proposed. An RMCL of 0.44 mg/l is proposed, based upon an AADI of 2.2 mg/l assuming 20 percent drinking water contribution.

C. RMCLS Not Proposed

1. Atrazine

Atrazine [6-chloro-N-ethyl-N'-(1-methylethyl)-1,3,5-triazine-2,4-diamine; CAS # 1912-24-9] is a herbicide and a plant-growth regulator. It is slightly soluble in water under normal conditions (33 mg/l at 27 °C). Its vapor pressure is low ($1.4x10^{-6}$ mm Hg at 30 °C). Domestic use of atrazine is estimated to range between 100 and 500 million pounds annually. About 96 percent of the domestically supplied atrazine is used on corn and soybeans.

Analytical Methods. Analytical methods available for analyzing atrazine in drinking water include the solvent extraction-gas chromatography technique.

Human Exposure. Very little data are available on atrazine levels in food. The 1971 and 1972 National Soils Monitoring Program reported that 1 percent of grain and vegetable samples from areas where atrazine is used contained atrazine in excess of the minimum detection level of 10 μg/kg. Atrazine residues are permitted on certain crops. If all foods contained atrazine residues up to the tolerance level, an adult might have a daily atrazine residue intake of up to 77 μg/day.

No information is available on the level of atrazine in ambient air.

One large surface water supply system sampled in the NORS contained 0.1 μg/l atrazine in its finished drinking water. During the NSP, 29 percent of the surface water systems contained atrazine in excess of the quantification limit of 0.1 μg/l. The range of positive values was 0.1–2.9 μg/l.

Atrazine was detected in six samples from drinking water supplies drawn from Northwestern Ohio rivers. Atrazine levels ranged from 0.087–15.9 μg/l; the average reported value was 6.76 μg/l.

Atrazine concentrations were detected during a study comparing the effectiveness of various types of water treatment for the removal of herbicides. Average concentrations of atrazine for the three supplies were 0.90, 2.1 and 3.31 μg/l, respectively. Peak concentrations were 1.22, 5.2 and 7.64 μg/l, respectively. Atrazine was found in a major water supply on the Mississippi River at 4.7–5.1 μg/l.

Two ground water systems analyzed in the NORS contained traces of atrazine. Ground water supplies in three midwestern States tested positive for atrazine, with concentrations typically in the range of 0.8 μg/l.

Health Effects. Insufficient toxicological data are available on the short-term effects of atrazine to calculate 1-day or 10-day assessments.

Atrazine appears to have low chronic toxicity in animals. In a 2-year chronic feeding study at 100 mg/l in the diet of rats, no gross or microscopic signs of toxicity were observed. The NAS (*Drinking Water and Health*, 1977. Vol. I) calculated an AADI for atrazine based upon an 80 week study (Innes, J.R.M., et al. 1969. Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice. A preliminary note. J. Nat. Cancer Inst. 42: 1101–1114) in mice in which a dose of 21.5 mg/kg/day was shown to result in an incidence of hepatomas of 4.24 percent in controls and 5.6 percent in atrazine treated animals. An ADI of 0.0215 mg/kg/day was determined based upon 21.5 mg/kg/day as a LOAEL and an uncertainty factor of 1,000 based on animal study. Based upon the NAS ADI, a provisional AADI of 0.75 mg/l was calculated, assuming consumption of 2 liters of water per day.

Atrazine has not been shown to be mutagenic in standard assays with microorganisms and studies on the carcinogenicity of the compound have shown inconclusive results. The IARC has not evaluated the carcinogenicity of atrazine. Atrazine has been classified in EPA's Group D, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon inadequate evidence from animals studies.

Only the Innes study is available on the health effects of atrazine and this study is inadequate to serve as the basis for the RMCL. Other studies submitted to EPA's Office of Pesticides Programs have been seriously questioned because of unscientific laboratory techniques. Due to the paucity of the toxicological data, an RMCL and primary regulation are not being proposed for atrazine. Atrazine will be reexamined for regulation when the toxicology data base is expanded.

2. 2,3,7,8-Tetrachlorodibenzo-p-dioxin

2,3,7,8-Tetrachlorodibenzo-p-Dioxin (2,3,7,8-TCDD; CAS # 828-00-2) is not manufactured purposefully; it is formed as a contaminant or impurity during chemical production or chemical pyrolysis. 2,4,5-Trichlorophenol (2,4,5-TCP), a chemical formed from 1,2,4,5-tetrachlorobenzene, is contaminated with 2,3,7,8-TCDD. 2,4,5-TCP is, in turn, used in the production of several herbidices, including 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) esters, and Silvex. Therefore, 2,3,7,8-

TCDD may be a contaminant of these herbicides. Additionally, TCDD may be formed as an impurity during the pyrolysis of chlorinated phenols, chlorinated benzenes, and polychlorinated diphenyl ethers.

Analytical Methods. Analytical methods available for analyzing 2,3,7,8-TCDD in drinking water include the solvent exraction-gas chromatography mass spectrometry technique.

Human Exposure. In theory, 2,3,7,8-TCDD could occur in food as a result of contamination of plant crops by herbicides such as Silvex or 2,4,5-T, consumption by livestock of 2,3,7,8-TCDD-contaminated forage or concentration of residues through the food chain. However, data on actual occurrence in food are rare. TCDD has been reported at levels of 4–70 ppt in the fat of cattle that had grazed on land treated with 2,4,5-T. 2,3,7,8-TCDD has also been detected in several species of commercial and non-commercial fish in several rivers and lakes in the United States. Levels of TCDD reported in fish and shellfish range from 1–700 ppt. The estimated maximum daily intake of 2,3,7,8-TCDD for individuals who regularly consume contaminated fish from the Great Lakes region might range from 0.39–8.4 ng/day.

Data on ambient air levels of 2,3,7,8-TCDD are limited. TCDD has been found in ambient air under special conditions. Air levels, ranging from 0.09 ng/m^3 to 0.07 ng/m^3, have been reported following agricultural application of Silvex. In addition, 2,3,7,8-TCDD was detected at an average level of 1,100 ppt in air at a disposal site near Jacksonville, Arkansas. Atmospheric emissions from municipal incinerators and from certain fires have been reported; however, data on ground level concentrations of 2,3,7,8-TCDD were not available.

Dioxin has not been detected in drinking water, as the physical/chemical characteristics of the compound suggest that it is relatively immobile and thus would not be expected to be found in drinking water. Data are not available showing occurrence in surface or ground waters.

Dioxin has been identified at more than 32 hazardous waste sites designated in complaints and consent decrees under the Comprehensive Emergency Response Compensation and Liability Act of 1980 (CERCLA) and the National Contingency Plan (40 CFR Part 300). The concentration of dioxin in the soil at one site was reported at 0.5 mg/kg and at levels of 20 mg/l in non-aqueous phase liquids in the dump.

In December 1983, EPA announced a National Dioxin Strategy to determine the extent of dioxin (primarily 2,3,7,8-TCDD) contamination throughout the country. The strategy provides a systematic framework under which the Agency will (1) study the nature of dioxin contamination throughout the U.S. and the risks to people and the environment, (2) clean-up dioxin-contaminated sites that threaten public health, (3) find ways to prevent future contamination, and (4) find ways to destroy or dispose of existing dioxins.

Health Effects. 2,3,7,8-TCDD is readily absorbed by mammals following either oral or dermal exposure and is rapidly distributed to tissues with a high lipid content. The liver represents a major site of accumulation in many species. Metabolism of 2,3,7,8-TCDD occurs slowly, with the polar metabolites excreted in the urine.

Characteristic non-carcinogenic effects resulting from exposure to 2,3,7,8-TCDD include thymic atrophy and weight loss. In certain species, liver damage is a major pathological effect.

One-day assessments were calculated based on a study in rats (Turner, J.N. and D.N. Collins. 1983. Liver Morphology in Guinea Pigs Administered either Pyrolysis Products of a Polychlorinated Biphenyl Transformer Fluid or 2,3,7,8-tetrachloro-dibenzo-p-dioxins. Toxicol. Appl. Pharmacol. 67:417–429) where a single day oral dose of 2,3,7,8-TCDD induced liver changes in female guinea pigs. Using a LOAEL of 0.1 μg/kg, an uncertainty factor of 1,000 and consumption of liter (child) or 2 liters (adult) of water per day, 1-day numbers of 1.0×10^{-3} μg/l for a 10 kg child and 3.5×10^{-3} μg/l for a 70 kg adult were calculated.

Ten-day assessments were calculated by dividing the one-day assessments by ten. Consequently, 10-day numbers of 1.0×10^{-4} μg/l for a 10 kg child and 3.5×10^{-4} μg/l for a 70 kg adult were calculated.

A provisional AADI has been calculated that is consistent with that developed by the Agency as indicated by the EPA, Ambient Water Quality Criteria for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (U.S. EPA, 1984. Ambient Water Quality Criteria for 2,3,7,8-Tetrachlorodiobenzo-p-dioxin. EPA 440/5–80–007) where it concluded that the 0.001 ug/kg dose in a three-generation reproduction study in rats by Murray, et al. (Murray, F.J., F.A. Smith, K.B. Nitsckle, C.G. Huniston, R.J. Kociba, and B.A. Schwetz. 1979. Three-generation Reproduction Study of Rats Given 2,3,7,8-Terachloro-p-dioxin (TCDD) in the diet. Toxicol. Appl. Pharmacol. 50:24–251), in conjunction with reproductive effects noted at 0.0015 ug/kg in a limited study with monkeys by Schantz, et al. (Schantz, S.L., D.A. Barsotti and J.R. Allen, 1979. Toxicological Effects Produced in Non-human Primates Chronically Exposed to Fifty Parts per Trillion 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD). Toxicol. Appl. Pharmacol. 48:A180), represents a LOAEL for adverse reproductive effects. A LOAEL of 0.001 ug/kg was selected, with an uncertainty factor of 1,000 based upon an animal study and consumption of 2 liters of water per day, resulting in an AADI of 3.5×10^{-6} mg/l.

The NAS (*Drinking Water and Health*, 1977. Vol. I) calculated an ADI of 0.0001 ug/kg day based on a 13 week oral treatment study in rats (Kociba, R.J., P.A. Keeler, C.N. Park, and P.J. Gehring, 1976. 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD): Results of a 13-week Study in Rats. Toxicol. Appl. Pharmacol. 35:553–574) using a NOAEL of 0.01 ug/kg/day, an uncertainty factor of 100 and consumption of 2 liters of water per day.

Mutagenicity tests have shown conflicting results with inconclusive evidence as to the mutagenicity of 2,3,7,8-TCDD. Animal studies have demonstrated the compound to be a potent animal carcinogen. Oral administration of 2,3,7,8-TCDD, either in the diet or by gavage, results in the production of hepatocellular carcinomas in female rats and both sexes of mice. In the National Toxicology Program bioassay (NTP, 1980. Bioassay of 2,3,7,8-Tetrachlorodibenzo-p-dioxin for Possible Carcinogenicity (Gavage Study). Carcinogenesis Testing Program. NCI, NIH, Bethesda, MD and NTP, Research Triangle Park, NC. Pub. No. 82–1765), rats and mice were dosed twice weekly by gavage with 2,3,7,8-TCDD in a corn oil-acetone solution. In male rats, a dose-dependent increase in the incidence of follicular-cell adenomas or carcinomas of the thyroid was observed. In female rats, observed increases in the incidence of subcutaneous tissue fibrosarcomas, adrenal cortical adenomas and hepatocellular carcinomas were observed only in the high dose group. Other studies have reported squamous cell carcinomas in both sexes of rats and follicular-cell adenomas of the thyroid in both male and female mice.

A number of reports and epidemiological studies have attempted to relate 2,3,7,8-TCDD exposure to human health effects. 2,3,7,8-TCDD has been implicated as the caustive agent for chloracne, hyperpigmentation, altered liver function and porphyria cutanea tarda in humans. In addition, questions have been raised regarding a possible relationship between 2,3,7,8-

TCDD exposure and cancer. The available studies do not establish a definite relationship between 2,3,7,8-TCDD and the development of tumors in humans, although an association has been suggested with soft-tissue sarcomas, lymphomas, and stomach cancer. The IARC have classified 2,3,7,8-TCDD in Group 2B; inadequate evidence for carcinogenicity in humans, sufficient evidence for carcinogenicity in animals and inadequate evidence for activity in short-term tests. 2,3,7,8-TCDD has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogens Risk Assessment, based upon positive results in studies in rats and mice.

EPA's CAG has derived estimates of risk from exposure to 2,3,7,8-TCDD in drinking water based upon a carcinogenicity study consisting of lifetime feeding of 2,3,7,8-TCDD in female rats (Kociba, R.J., D.G. Keyes, J.E. Berger, et al. 1977. Results of a Two-year Chronic Toxicity and Oncogenicity Study of 2,3,7,8-Tetrachlorodibenzo-p-dioxin in Rats. Toxicol. Appl. Pharmacol. 46:279–303). A q^*_1 of 1.56×10^5 $(mg/kg/day)^{-1}$ was calculated by the multi-stage model for this risk assessment. This is the geometric mean of $2q^*_1$ calculations based on the review of tissue slides by two independent pathologists and corrected for early mortality. The OHEA risk estimate is shown in Table 13.

CAG (U.S. EPA, Health Assessment Document for Polychlorinated Dibenzo-p-dioxin, May 1984. EPA–600/8–84–014A) has also derived risk estimates for 2,3,7,8-TCDD based on the same study using other models. The comparison for a risk estimate from exposure to a 2,3,7,8-TCDD level of 10^{-5} ug/kg/day is given below:

Dose (μg/kg/day)	95 percent upper confidence limit of additional risks		
	Multi-stage model/one-hit model [1]	Weibull	Log-probit
10^{-4} [2]	1.5×10^{-4}	9.7×10^{-5}	7.7×10^{-4}
10^{-5} [3]	1.6×10^{-4}	1.3×10^{-4}	4.4×10^{-5}

[1] Both models gave identical results.
[2] Based upon Kociba analysis of pathology, corrected for early mortality.
[3] Based upon Squire analysis of pathology, corrected for early mortality.

The EPA water quality criterion for 2,3,7,8-TCDD for carcinogenic endpoints (U.S. EPA. 1984. Ambient Quality Criteria for 2,3,7,8-Tetrachlorodibenzo-p-dioxin. EPA 440/5–80–007) is 1.3×10^{-8} μg/l based on an estimated human lifetime cancer risk of 1×10^{-6} and assuming daily consumption of 2 liters of water and 6.5 g of fish and shellfish. The study and statistical model used for this risk assessment were the same as those used for the risk assessment for 2,3,7,8-TCDD previously described. The FDA has issued a Health Advisory (FDA, 1983. Statement by S.A. Miller, Director, Bureau of Foods, FDA, before the Subcommittee on Natural Resources, Agriculture Research and Environment, U.S. House of Representatives, June 30) in which fish containing >50 ppt 2,3,7,8-TCDD should not be consumed and fish containing <25 ppt 2,3,7,8-TCDD do not pose a serious health concern. A tolerance of 0.05 ppm for hexachlorophene methylenebis (2,3,6-trichlorophenol) in or on feedstock cottonseed has been set with the condition that the technical grade material contain no more than 0.1 ppm, 2,3,7,8-TCDD (40 CFR 180.302).

2,3,7,8-TCDD has not been detected in drinking water supplies. The compound is not mobile in runoff or soils and has not been found in ground water or surface water that is a potential source of drinking water. Due to the limited occurrence and potential for occurrence in drinking water, an RMCL and primary regulation is not being proposed for 2,3,7,8-TCDD.

Question for Comment:

1. Are there any data to suggest that 2,3,7,8-TCDD is known or likely to be found in drinking water supplies?

3. Endrin

Endrin (1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a, 5,6,7,8,8a-octa-hydro-1,4-endo,endo-5,8-dimethanonaphthalene; CAS # 72–20–8; current MCL is 0.2 μg/l) is a commercially used insecticide and rodenticide. The solubility of endrin in water is 0.25 mg/l. Endrin is persistent and is concentrated through the aquatic food chains.

Endrin was only widely used in the U.S. The EPA issued a notice of rebuttable presumption against registration and continued registration (RPAR) of endrin-containing products in 1976. It included three risk presumptions—risk of significant population reductions of non-target organisms, acute toxicity to wildlife, and teratogenicity. After review, the Agency determined that the offsetting economic, social or environmental benefits were not great enough, and endrin was cancelled for a number of uses and registration for new uses of endrin were denied. Endrin is presently registered only for the control of cutworms, grasshoppers and moles; however, the sole Endrin manufacturer has ceased production for use in the U.S. Environmental concentrations of endrin appear to be decreasing due to these use restrictions.

Analytical Methods. Analytical methods available for analyzing endrin in drinking water include the solvent extraction-gas chromatography technique.

Human Exposure. In FDA's compliance program report for FY 77 on pesticides and metals, endrin was detected in 2.1 percent of the samples tested. In the FDA FY 79 total dietary study for adults and infants, no endrin was detected in any of the foods sampled. One residue was detected in an oils and fats sample at a level of 1 μg/l for the toddler diet. According to the USDA, in 1982–1983, 0.3 percent of the fat tissue from various animal species intended for human consumption contained endrin levels ranging from 0.01–0.10 μg/kg.

Tolerances for residues of endrin as set by EPA's Office of Pesticide Programs, in or beets, broccoli, brussels sprouts, cabbage, cauliflower, cottonseed, cucumbers, eggplant, pepper, potatoes, squash and tomatoes are 10 ppm.

Ambient air studies between 1970–1975 reported endrin levels as high as 39.3 ng/m³.

Endrin is rarely detected in drinking water. The compound has been detected in three surface water supplied drinking water systems in one State. None of the surface or ground water systems analyzed during the NSP or the RWS contained detectable levels of endrin. National compliance reports with the NIPDWR show that no system sampled reported endrin in excess of the MCL of 0.2 mg/l.

Health Effects. At high dose levels, endrin has been shown to accumulate in liver, brain, kidneys, and fat, while at lower dose levels endrin is quickly metabolized and eliminated from the body. The major toxicant in mammals is considered to be the metabolite 12-ketoendrin.

One-day assessment were calculated for endrin based upon a study in squirrel monkeys (Revzin, 1968. Effects of Chronic Endrin Administration on Brain Electrical Activity in the Squirrel Monkey. Fed. Proc. 27:697) where 0.2 mg/kg endrin was administered daily for 7 days and alterations in the EEG were recorded. No effects were noted at this dose for shorter term exposure. Using 0.2 mg/kg/day as the NOAEL for 1-day exposure, an uncertainty factor of 100 and consumption of 1 liter (child) or 2 liters of water (adult) of water per day, 1-day numbers of 0.02 mg/l for a 10 kg child and 0.07 mg/l for a 70 kg adult were calculated.

Ten-day assessment were calculated based upon a study (Nelson, et al. 1956. Serum Alkaline Phosphatase Levels, Weight Changes, and Mortality Rates of

Rats Fed Endrin. J. Agric. Food & Chem. 4:696) in rats exposed for 1 or 2 weeks to 5 ppm (0.05 mg/kg/day) endrin in the diet. The body weight of the exposed animals was decreased relative to controls. Using 0.05 mg/kg/day as a NOAEL, an uncertainty factor of 100, and consumption of 1 liter (child) or 2 liters of water per day (adult), 10-day numbers of 0.005 mg/l for a 10 kg child and 0.018 mg/l for a 70 kg adult were calculated.

A provisional AADI for endrin was derived based upon a feeding study (Treon, et al. 1955. Toxicity of Endrin for Laboratory Animals. J. Agric. Food & Chem. 3:842) in which dogs were exposed for 18.7 months to 1, 3, or 4 ppm endrin in the diet. Based on measured food intake, the daily dose varied from 0.045 to 0.12 mg/kg bw for the 1 ppm group, 0.12 to 0.25 mg/kg bw for the 3 ppm group and 0.15 to 0.21 mg/kg bw for the 4 ppm group. Increases in heart and kidney weights were noted at 3 and 4 ppm but not at 1 ppm. Using 0.045 mg/kg bw (1 ppm) as the NOAEL, an uncertainty factor of 1000 based upon an animal study with few animals per dose level, and consumption of 2 liters of water per day, a provisional AADI of 0.002 mg/l was calculated.

Endrin was not shown to be mutagenic in microbial systems with or without microsomal activation. The potential carcinogenic effects of endrin were evaluated in several animal studies. The results were negative in four studies, including the National Cancer bioassay (NCI. 1979. Bioassay of Endrin for Possible Carcinogenesis. Tech. Rep. Ser. 12, NCR–CG–TR–12). The only study (Deichmann, et al. 1970. Tumorigenicity of Aldrin, Dieldrin and Endrin in the Albino Rat. Ind. Med. 39:426) reporting positive results was a rat study in which endrin was administered at concentrations of 0, 0.1, 5, 20 or 25 ppm. The total number of malignant tumors was increased in all exposed groups. No more than 2 tumors/group, however, were reported for one site. Moreover, no dose response was apparent with the greatest number of tumors occurring in the 0.1 ppm group. The NAS (*Drinking Water and Health*, 1977. Vol. I) have stated that there are insufficient data to permit a statistical extrapolation of cancer risk for endrin and that endrin is a suspect animal carcinogen. The IARC have not addressed the carcinogenicity of endrin. Endrin has been classified in EPA's Group E, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon the negative results from four studies including the NCI bioassay.

EPA's ambient water criterion for endrin (U.S. EPA. 1980. Ambient Water Quality Criteria for Endrin. EPA/440/5–80–047) for human health is 0.001 mg/l. This was based upon the same study which was used to derive the provisional AADI and a value of 0.001 mg/l was recommended because it was the maximum allowable concentration proposed by the Public Health Service for drinking water. The WHO (1973) established as a guideline a maximum intake of 2 μg/kg/day, or 138.2 μg/day, for a 69.1 kg person. The WHO has not established a drinking water guideline for endrin.

The MCL, under the National Interim Primary Drinking Water Regulations, is 0.002 mg/l. The provisional AADI is slightly higher than the interim MCL due to the fact that the provisional AADI is calculated based on the measured food intake of a dog, while the MCL was calculated based upon the assumed food consumption of a dog, both based upon the same study (Treon, et al. 1955. Toxicity of Endrin for Laboratory Animals. J. Agric. Food & Chem. 3:842).

Endrin is rarely detected in drinking water and has been cancelled for new uses. The compound is not considered to be very mobile and thus EPA is not proposing an RMCL for endrin.

Question for Comment:

1. Is there sufficient occurrence and potential for occurrence in drinking water to propose an RMCL foe endrin?

4. Hexachlorobenzene

Hexachlorobenzene (CAS # 118–74–1) has a vapor pressure of 1.09×10^{-5} mm Hg (20 °C). It has a very low aqueous solubility (6 ug/l at 25 °C). Hexachlorobenzene is no longer produced in the United States. However, approximately 2 to 5 metric tons of hexachlorobenzene are generated annually as a waste byproduct of chlorinated solvent and pesticide production. The primary use of hexachlorobenzene in 1972 was as a fungicide. The majority of these formulations are no longer produced. Other industrial uses have included dye manufacturing, an intermediate in organic synthesis, porosity controller in the manufacture of electrodes, a wood preservative and an additive in pyrotechnic compositions for the military. Since hexachlorobenzene is no longer produced in the United States, commercial uses of hexachlorobenzene have virtually ceased.

Analytical Methods. Analytical methods available for analyzing hexachlorobenzene in drinking water include the solvent extraction-gas chromatography technique.

Human Exposure. Hexachlorobenzene has been a contaminant of concern because of its occurrence in human tissue and the milk from nursing mothers. The compound has been found in adipose tissue and milk of cattle raised in the vicinity of industrialized regions in Louisiana, and in adipose tissue of sheep in western Texas and California. Hexachlorobenzene has also been found in fish and birds.

Hexachlorobenzene has been found in ambient air around production sand waste disposal sites.

Limited information is available on levels of hexachlorobenzene in finished drinking water supplies. Hexachlorobenzene was detected in a Regional survey in two finished water supplies at levels of 4 and 6 ng/l. In the NSP, the compound was not detected.

Health Effect. Hexachlorobenzene is readily absorbed and distributed to tissues that have high lipid content. The adipose tissue accumulates the greatest concentrations of hexachlorobenzene, although bone marrow and skin also accumulate the compound. Hexachlorobenzene is metabolized slowly into other chlorinated benzenes, chlorinated phenols and other minor metabolities. The excretion of hexachlorobenzene is characterized by an initial rapid phase followed by a very slow phase.

Chronic toxicity studies in animals have shown a significant increase in liver and kidney weights in hexachlorobenzene-treated animals, as well as hepatic and renal lesions. Increased prophyrin levels in the liver and the urine have been reported in several species.

Porphyria cutanea tarda (PCT) has been associated with exposure of humans to hexachlorobenzene. An epidemic of hexachlorobenzene-induced PCT occurred in Turkey, from exposure during 1955 to 1959 to contaminated seed wheat used for food. It has been estimated that 0.05 to 0.2 g of hexachlorobenzene was consumed per day. PCT is a disease of disturbed porphyrin metabolism manifested by cutaneous lesions and hyperpigmentation. Follow-up studies conducted 20 to 25 years after the onset of porphyria showed that a few patients still had active porphyria, whereas greater than 50 percent exhibited hyperpigmentation, scarring and other signs of hexachlorobenzene toxicity. Hexachlorobenzene residues were also found in the blood, fat or breast milk of some patients.

One-day and 10-day assessments were calculated based on a study (Kuiper-Goodman, et al. 1977. Subacute

Toxicity of Hexachlorobenzene in the Rat. Toxicol. Appl. Pharmacol. 40:529–549) where porphyrin, liver lesions and other toxic effects were found in rats fed hexachlorobenzene for 15 weeks and held to 48 weeks. Using a NOAEL of 0.5 mg/kg, an uncertainty factor of 100 and consumption of 1 liter (child) or 2 liters (adult) of water per day, 1-day and 10-day assessments of 0.050 mg/l for a 10 kg child and 0.175 mg/l for a 70 kg adult were calculated.

An AADI was calculated for hexachlorobenzene based upon a 130 week feeding study in rats (Arnold, et al. 1983. Long-term Toxicology of Hexachlorobenzene in the Rat. In preparation). A NOAEL of 1.6 ppm (0.084 mg/kg/day) was selected based upon liver and kidney lesions and increased mortality at higher doses. An uncertainty factor of 100 was applied and consumption of 2 liters of water per day, resulting in an AADI of 0.029 mg/l.

Hexachlorobenzene has not been shown to be mutagenic in the *Salmonella* histidine reversion assay, but was reported mutagenic in a yeast *S. cerevisiae* assay. Hexachlorobenzene has been shown to be carcinogenic in animal studies, showing an increased incidence of malignant tumors of the liver in hamsters and rats, as well as inducing hepatomas in mice, rats and hamsters.

The IARC has classified hexachlorobenzene in Group 2B; inadequate evidence for carcinogenicity in humans and sufficient evidence for carcinogenicity in animals. Hexachlorobenzene has been classified in EPA's Group B2, according to EPA's Proposed Guidelines for Carcinogen Risk Assessment, based upon positive results in studies in rats, mice and hamsters.

The NAS (*Drinking Water and Health*, 1983. Vol. V) calculated upper 95 percent limits of cancer risk based on carcinogenicity data in a study with male and female mice. In the external review draft of the EPA Health Assessment Document for Chlorinated Benzenes (April 1984, EPA–600/8–84–015A), the CAG has calculated risk estimates based on hepatocellular carcinomas in a lifetime dietary feeding study with female rats using them 95 percent upper limit of the multi-stage model. The study used by CAG is more recent and the CAG number gives a more conservative risk estimate. The NAS and CAG risk estimates are shown in Table 13.

Point estimates 95 percent upper limit estimates based on several models were also calculated by the CAG. Using a lifetime exposure to 0.0 mg hexachlorobenzene/kg body weight/day, these estimates are as follows:

Assumption of human equivalent dose	Models	Risk at 0.01 mg/kg/day
Body weight basis	Multi-stage	2.7×10^{-4} (a) (2.2×10^{-4} (b))
	Probit	3.6×10^{-4} (1.3×10^{-10})
	Weibull	1.2×10^{-4} (2.5×10^{-5})
	One-hit	2.7×10^{-4} (2.2×10^{-4})
Surface area basis	Multi-stage	1.7×10^{-4} (1.4×10^{-4})
	Probit	5.2×10^{-4} (4.1×10^{-4})
	Weibull	5.0×10^{-4} (1.3×10^{-4})
	One-hit	1.7×10^{-4} (1.4×10^{-4})

(a) 95% upper limit.
(b) Point estimate.

The WHO guideline for hexachlorobenzene (1984) is 0.01 μg/l based upon a risk of one additional case of cancer per 100,000 population, assuming a daily consumption of 2 liters of drinking water.

Hexachlorobenzene has rarely been detected in drinking water and the compound is not considered to mobile. For these reasons, EPA is not proposing a primary regulation for the compound.

Question for Comment:

1. Is there sufficient occurrence and potential for occurrence in drinking water to propose an RMCL for hexachlorobenzene?

5. Simazine

Simazine (6-chloro-N,N'-diethyl-1,3,5-triazine-2,4-diamine; CAS # 122–34–9) is a herbicide applied to field crops and on non-agricultural sites. Irrigation or rainfall moves the chemical into the root zone of weeds where it is active. It may also be used as an algacide or to control submerged weeds. Because simazine has a low vapor pressure, there is little tendency for simazine to enter air directly during and following application, spillage or disposal. In the U.S., approximately 61 percent of simazine is applied in commercial agricultural operations; 39 percent is applied to non-agricultural sites (aquatic applications included).

Analytical Method. Analytical methods available for analyzing simazine in drinking water include the solvent extraction-gas chromatography technique.

Human Exposure. There are few data on the levels of simazine in the U.S. food supply. Six domestic food samples were analyzed for simazine in the FDA FY 77 pesticides and metals program. None of these samples contained simazine levels in excess of the quantitation limits (between 10 and 100 μg/kg).

No data were found on the levels of simazine in air.

Simazine has been reported in drinking water from surface supplies. In the NSP, conducted from June 1977–March 1981, 12 percent of finished drinking water samples collected from surface water systems contained simazine; levels ranged from 0.1–4.4 μg/l.

Levels of simazine ranging from 0.026–0.883 μg/l were detected in five drinking water samples collected from a surface water supply in one State during peak periods of pesticide usage and maximum pesticide export.

Simazine concentrations reported for drinking water samples collected from three treatment plants in another State in 1983 ranged from 0.077–0.30 μg/l; peak concentrations ranged from 0.13–0.63 μg/l for the three reports.

Simazine has also been found in ground water. One of the 12 ground water systems sampled in the NSP contained 1 μg/l. Six out of 166 wells in California were found to be contaminated at levels between 0.5–3.5 μg/l.

Health Effects. There is a lack of data on the health effects of simazine in animals and humans. In one study (U.S. EPA, 1976. Draft Report, Initial Scientific and Microeconomic Review, Simazine. Office of Pesticide Programs, EPA Contract No. 68–01–1904), simazine fed to rats for 2 years at 1.0, 10 and 100 mg/l did not produce any difference between treated and control animals in gross appearance or behavior.

The NAS (*Drinking Water and Health*, 1977. Vol. I) calculated an ADI for simazine based upon an 80 week study (EPA, No. 68–01–1904) in mice in which a dose of 215 mg/kg/day was shown to result in an incidence of hepatomas of 4.2 percent in controls and 5.6 percent in simazine treated animals. An ADI of 0.215 mg/kg/day was determined based upon 215 mg/kg/day as a LOAEL and an uncertainty factor of 1,000 based upon an animal study.

Simazine was negative in mutagenicity studies with four strains of *Salmonella typhimurium* and the results of carcinogenicity studies on the compound have been inconclusive. The IARC has not evaluated the carcinogenicity of simazine. Simazine has been classified in EPA's Group D, according to EPA's Proposed guidelines for Carcinogen Risk Assessment, based upon inadequate data from animal studies.

Due to inadequate toxicology data, an RMCL and primary regulation will not be proposed for simazine. The study used by the NAS to calculate an ADI

has since been found to be invalid and no new data are available to determine an AADI.

6. Other SOCs

Adipates, dalapon, dibromomethane, dinoseb, diquat, endothall, glyphosate, hexachlorocyclopentadiene, PAHs, phthalates, picloram, 1,1,2-trichloroethane and vydate were included in the list of SOCs under consideration for Revised Regulations in the ANPRM. Data collection efforts on occurrence/human exposure and potential health effects have not yet been completed on these substances and these SOCs will be considered in later phases of the Revised Regulations.

IX. Impact of This Regulation

The proposal of an RMCL is different than proposal of an MCL in that an RMCL is, by law, to be based only on health and safety considerations, while an MCL is to take costs into consideration. Therefore, this RMCL proposal notice does not include an analysis of the economic impacts of various possible RMCLs. However, the probable impacts of the various MCL alternatives will be analyzed and reported at the time an MCL is proposed.

The report will include an analysis of the impacts of the various alternatives on the water supply industry vis-a-vis capital costs of technology, operating and maintenance costs and the feasibility of financing new treatments. Additionally impacts on the consumer and the nation as a whole will be analyzed.

Under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., I certify that this action will not have a significant impact on a substantial number of small entities. This proposed action will have no economic impact because these are non-enforceable health goals.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This proposed action does not constitute a "major" regulatory action because it will not have a major financial or adverse impact on the community and it is a non-enforceable action. This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

There are no paperwork burdens associated with this regulation, and there are no information collection requirements subject to the provisions of the Paperwork Reduction Act (144 U.S.C. 3501 *et seq.*).

X. Public Docket

All supporting materials pertinent to the development of this proposal are included in the Public Docket located at EPA headquarters, Washington, DC. The Public Docket is available to the public and the public should contact the Dirnking Water Regulations Docket Manager for access. It would have been desirable to publish in this notice the list of supporting materials, but the Public Docket is voluminus and a listing of the documents in this notice would be much too long. However, references on occurrence of chemicals in drinking water, analytical methods and health effects criteria document are cited below as these documents provide summaries of data used in determining the proposed RMCLs. Other materials in the Public Docket include such documents as the following:

- Public comments on the ANPRM.
- Transcript of the December 13, 1983, Public Meeting.
- Report and background materials for the four public workshops, Fall 1983.
- Transcripts and minutes of NDWAC Meetings.
- Summaries of meetings, telephone calls from outside EPA.
- Letters to/from public.
- Technical Reports.
- Other supporting materials.

For each inorganic and organic chemical for which RMCLs are proposed, a health effects criteria document has been prepared and is available to the public. For example, a typical reference listing would be as follows:

EPA, Office of Drinking Water, Criteria and Standards Division, Draft Health Effects Criteria Document for *Lead*, September 1984.

Similarly, documents summarizing the occurrence of inorganic and organic chemicals in drinking water have been prepared for each chemical for which RMCLs are proposed. Individual documents have been prepared for inorganic chemicals whereas one document including all organic chemicals has been prepared. A typical reference listing for the inorganics occurrence document would be as follows:

EPA, Office of Drinking Water, Criteria and Standards Division, Draft Occurrence/Exposure of *Lead* in Drinking Water, September 1984.

The SOC occurrence document is referenced as follows:

EPA, Office of Drinking Water, Criteria and Standards Division, Draft Occurrence/Exposure of Synthetic Organic Chemicals (including pesticides) in Drinking Water, September 1984.

Summaries of the analytical methods, occurrence in drinking water and health effects in a single document have been prepared for each microbial contaminant for which RMCLs are proposed. A typical reference listing would be as follows:

EPA, Office of Drinking Water, Criteria and Standards Division, "Analytical Methods, Occurrence, and Health Effects of *Total Coliforms* in Drinking Water, September 1984.

Other pertinent references available in the public docket include the following:

"Standard Methods for the Examination of Water and Wastewater," 15th Edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1975.

Annual Book of ASTM Standards, Part 31, Water, American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.

Bellar, T.A., Lichtenberg, J.J. "The Determination of Halogenated Chemical Indicators of Industrial Contamination in Water by the Purge and Trap Method: Method 502.2," U.S. EPA, EMSL #600/4-81-059.

Bellar, T.A., Lichtenberg, J.J. "The Analysis of Aromatic Chemicals in Water by the Purge and Trap Method: Method 503.1," U.S. EPA, EMSL, EPA 600/4-81-057.

EPA, EMSL. "Methods for Chemical Analysis of Water and Wastes" (EPA 600/4-79-020, March 1979). Available from ORD Publications, CERI, EPA, Cincinnati, Ohio 45268.

National Academy of Sciences, "Drinking Water and Health, Volume I (1977), II (1980), III (1981), IV (1981), V (1983).

IARC, 1979. IARC Monographs on the evaluation of the carcinogenic risk of chemicals to humans: some halogenated hydrocarbons. Vol. *20*: 14-15.

IARC, Approaches to Classifying Chemical Carcinogens According to Mechanism of Action, Technical Report No. 83/001. April 1983.

NCI, "Policy of Risk Assessment of the Health Effects of Hazardous Exposures to Populations," Subcommittee on Environmental Carcinogens, National Cancer Advisory Board, 1983.

Assessment of Microbiology and Turbidity Standards for Drinking Water (Workshop Proceedings), EPA, ODW, 1983.

Evaluation of the Microbiology Standards for Drinking Water, NTIS, Accession No. PB 297119.

49 **Federal Register**, 46294 (November 23, 1984). EPA's Proposed Guidelines for Carcinogen Risk Assessment.

The above health effects criteria documents and summary documents for

the microbials are available for viewing at EPA headquarters or in any of the ten EPA regional offices as listed in the beginning of the notice. Copies of these documents can be obtained for a fee at NTIS, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll free telephone number is 800/336-4700; local 703/487-4650.

XI. Request for Public Comment

EPA requests public analysis, comments and information on all aspects of this proposal. The questions for which comment is being specifically solicited are listed below. Comment will be of great assistance to EPA in formulating a protective and practical approach to reducing human exposure to contaminants in drinking water.

• Is the regulatory approach in this proposal appropriate under the SDWA, i.e., set regulations for contaminants (1) that pose a health risk to consumers in drinking water, and (2) that have the potential for occurring in drinking water (e.g., pesticides registered for use in or near drinking water supplies) or that are known to occur on a regional or national basis but not necessarily at (a) high frequencies or (b) high levels.

This approach would result in a comprehensive list of regulated contaminants which would provide a standard by which to assess drinking water when contamination is found. Inherent in this approach is full public participation in the standard setting process. The alternate regulatory approach which would set regulations for contaminants that pose a health risk in drinking water but only for those contaminants detected at relatively high frequencies at levels near the level of health concern. Health Advisories would be provided as needed for those contaminants for which regulations were not developed.

• Do the proposed RMCLS represent a level such that "no known or anticipated adverse effect would result with an adequate margin of safety"?

—Is the three-category approach for setting RMCLs an acceptable method for factoring strength of evidence in the RMCL determinations?

—Are the classifications of the chemicals scientifically acceptable?

—For non-carcinogens, is the approach and actual studies used for computing the AADIs scientifically acceptable? Are the safety factors used in the ADI calculcation for each contaminant scientifically acceptable? Where data are not available, is providing for an assumed contribution of 20 percent from drinking water appropriate?

—Should RMCLs for probable human carcinogens be set at zero? If RMCLs are set at zero, what guidance, if any, should be provided on the actually attainable target levels in drinking water?

—For compounds with equivocal evidence of carcinogenicity, should the RMCLs be set based upon AADIs, cancer risk levels or some other method?

• The term "Acceptable Daily Intake" or "ADI" has been criticized as connotating an "acceptable" level of exposure to which any level greater than the ADI is "unacceptable". This is contrary to the views of most scientists who generally interpret the ADI as a "ballpark figure" which represents a level of exposure which is not likely to result in adverse effects in humans. It is viewed as a soft estimate in that exposures somewhat higher than the ADI are generally not expected to result in adverse effects; only if the ADI is significantly exceeded would one expect such negative consequences.

In order to help prevent misinterpretation, the term "ADI" could be replaced with the term "reference dose". This term was derived based upon the process of generating the ADI in which the NOAEL based upon animal data is divided by an uncertainty factor to generate a human dose. This derived human dose then serves as a point of reference, a benchmark against which other human doses are compared.

Comment is requested on the use of the term "Reference Dose" to replace ADI.

• The term "Adjusted Acceptable Daily Intake" or "AADI" has been used to represent a total allowable exposure as measured in mg/l drinking water, but is derived directly from the ADI which is measured in mg/kg body weight/day. This modification of units of measurement for a concept that is traditionally expressed in mg/kg/day has led to some confusion and criticism, particulary from the toxicological community. It has been proposed that a more appropriate term be created, such as "Drinking Water Equivalent Level (DWEL) or "Drinking Water ADI" (DWADI). These terms would allow a shift to a medium-specific unit (mg/l drinking water) and define a concentration in drinking water which, during the entire lifetime of the human, would be estimated to be without appreciable risk.

Comment is requested on the use of the terms "Drinking Water Equivalent Level" or "Drinking Water ADI" to replace AADI.

• How should exposure to multiple contaminants in drinking water be addressed to in the Revised Regulations? Because of concerns of synergistic effects should a RMCL and MCL be set for total SOCs or total IOCs?

• Are the levels proposed for RMCLs for microbial contaminants appropriate?

• Is the approach being proposed for *Giardia* and viruses which would set RMCL and MCLs, and monitoring but also require a treatment technique regulation of filtration and disinfection for surface waters and disinfection for ground waters appropriate? The public water system would have a choice of meeting the MCLs vs. the treatment technique requirement. What criteria would be appropriate upon which to base a variance from the treatment technique requirements for surface water systems? for ground water systems?

• Should certain types of non-community systems, such as schools and factories, be required to meet the MCLs that apply to community water systems?

• Are the cited analytical methods cited available (i.e., economically and technologically feasible) to ascertain the level of those contaminants for which RMCLs are proposed?

A public hearing will be held at EPA in Washington, DC, on January 28 and 29, 1986, in Conference Room 1, adjacent to the Washington Information Center for the interested public to comment and provide information and data on these proposed regulations.

EPA recognizes that many significant scientific and regulatory questions of the issue of the control of contaminants in drinking water. The Agency has attempted in this proposal to portray current scientific uncertainties in a measured and objective manner. In this way, any data gaps or errors in logic which may exist can be identified and corrected. Careful review of and thoughtful comment on the information in this proposal and reference materials is encouraged.

Lists of Subjects in 40 CFR 141

Chemicals, Intergovernmental relatives, Radiation protection, Reporting and record keeping requirements, Water supply.

Dated: October 10, 1985.

Lee Thomas,

Administrator.

Appendix A—Summary of Public Comments Pertinent to the Proposed Recommended Maximum Contaminant Levels (RMCLS) for Organic, Inorganic and Microbial Contaminants in Drinking Water

The following is a summary and discussion of the principal public comments to EPA's proposed rule for the establishment of RMCLs for organic, inorganic, and microbial contaminants in drinking water. EPA specifically solicited comments on the following issues in its October 5, 1983, Advance Notice of Proposed Rulemaking (ANPRM):

1. Is the three-tiered approach appropriate? What criteria should be used to determine which contaminants should be in each category?

2. For which contaminants should regulations be set? Into which category should the contaminants be included: Category I, Category II, of Category III as described? What levels for the RMCLs would be appropriate?

3. Should a treatment technique requirement of disinfection be set for all ground water systems? Should a treatment technique requirement of filtration be set for surface water systems?

4. Is using the ADI an appropriate method for establishing RMCLs for non-carcinogens?

5. What safety factors should be used in conjunction with chronic toxicity data in setting RMCLs for non-carcinogens?

6. What approach should be used to set RMCLs for carcinogens?

7. Is waiving certain MCLs when susceptible populations are not affected an appropriate approach?

8. Should separate or different MCLs be considered for certain contaminants for non-community water systems?

9. Are analytical methods available for contaminants under consideration?

EPA received 133 written comments during the 90+ day public comment period and three statements were presented at the public meeting held in Washington, D.C., on December 13, 1983. The statements presented at the public meeting have been incorporated with the written comments submitted. These 135 comments included 62 industries and industry associations, 33 water utilities, 11 state governments and state organizations, 6 public interest groups, 4 private citizens and 11 from other groups including some federal government agencies.

The following discussion summarizes comments pertinent to the RMCL proposal (i.e., primarily occurrence, health effects, and analytical methods) received on the ANPRM for revised drinking water regulations. Comments on such items as monitoring and GAT are pertinent to MCLs and will be summarized in the MCL proposal.

(1) Is the three-tiered approach appropriate? What criteria should be used to determine which contaminants should be in each category?

Thirty-four comments addressed this issue. The majority of commenters favored the three-tiered approach because this is a sound regulatory approach which offers States monitoring flexibility and permits States to optimize available resources. Most of these commenters agreed with the criteria for each category, as stated in the ANPRM. A few commenters suggested some recommendations to this approach, as outlined in the ANPRM, which included:

- retain the distinction between community and non-community water supplies;
- additional categories should be added in the future, if necessary;
- Category I should read, "have an adverse effect," not "*may* have an adverse effect";
- monitoring frequency for Category II chemicals should be established by the State using guidelines set by EPA;
- monitoring should be based on geographical areas within a State, type and source of supply, historical data, and system size; and
- a national monitoring program should be carried out before categorizing the chemicals.

A few commenters did not favor the three-tiered approach. One commenter felt "the concept is needlessly complicated and may result in a lengthy, unreasonable, and superfluous debate over which category a chemical should be in." They suggested only two categories—MCL or no MCL. Their reasoning was that primacy agencies could adjust monitoring requirements. Furthermore, they recommended EPA put a time limit on the applicability of health advisories so they will either be updated, establish a MCL if necessary or withdraw the health advisory and provide reasons for doing so. Some of the other commenters who did not favor this approach were also concerned about the health advisory program but for different reasons. They felt that the health advisories were being misused by other EPA program offices and they go beyond the statutory authority of the Safe Drinking Water Act (SDWA), which does not provide for a program of quasi-regulatory guidance to state and local officials. Their recommendations were for health advisories to receive independent scientific peer review and for the SDWA to be amended to formalize the health advisory process.

(2) For which contaminants should regulations be set? Into which category should the contaminants be included: Tier I, Tier II or Tier III as described? What levels for the RMCLs would be appropriate?

The majority of written comments received addressed which contaminants should regulations be set, specifically MCLs. The comments received did not distinguish between RMCLs and MCLs, however, it is appropriate to discuss for which contaminants should regulations be set for even though the comments pertain to MCLs, not RMCLs. Concerning occurrence data, five commenters felt EPA should broaden its data base. A single, large scale survey to determine the occurrence of the various constituents was suggested. Occurrence studies should be broadened to include statistically valid, geographically randomized sample of every system size, including ground and surface water sources. It was also proposed that EPA adopt a chemical data reporting system for all substances identified under other PEA programs. EPA should then provide this information to the primacy agencies.

Sixteen comments addressed the tier in which the contaminants should be included: Tier I, Tier II or Tier III. The majority of commenters felt that the turbidity and total coliform standards should be in Tier I to protect against waterborne disease. The inorganic chemicals currently regulated by EPA were placed predominantly in Tier II to allow for monitoring flexibility, but a few commenters recommended deleting a few of the MCLs and developing health advisories instead (Tier III). The several contaminants listed in the ANPRM that were already included in the secondary drinking water regulations were all placed in Tier III along with several other inorganic chemicals. A few commenters felt that the synthetic organic chemicals should either be in Tier II or III, depending on occurrence and adverse health effects information. The distribution of chemicals for Tier I, II and III was as follows:

Chemical	Tier		
	I	II	III
Arsenic		8	2
Barium		11	2
Cadmium		10	
Chromium		10	2
Lead	2	8	
Mercury		8	2
Nitrate	2	8	
Silver		5	1
Selenium		11	2
Coliforms	9		

Chemical	Tier		
	I	II	III
Turbidity	5	1	
Aluminum			5
Antimony			4
Asbestos			5
Beryllium			1
Copper			5
Cyanide			3
Molybdenum			4
Nickel			1
Sodium			8
Sulfate			3
Thallium			1
Vanadium			3
Zinc			5
Viruses			1
Legionella			1
Giardia			1
SOCs	1	7*	

*II or III.

In order to present a summary of the comments which addressed which contaminants should regulations be set, the discussion will be summarized per chemical.

Inorganics

Arsenic

Eleven commenters addressed the present arsenic MCL of 0.05 mg/l. The majority of commenters felt the standard should remain the same because it appears that both valences are toxic and there is no available analytical method to differentiate. However, three commenters felt that due to differing toxicities, separate MCLs for trivalent and pentavalent arsenic should be established, if an acceptable means of analysis is available to differentiate the two compounds.

Two commenters felt the MCL should be deleted and EPA should prepare a Health Advisory. Their reasoning is that studies have been done in their cities because they have levels of arsenic in their drinking water above the MCL. The results of these studies have shown no ill-effects from ingesting these arsenic levels over many years.

Barium

Twenty-five commenters addressed the present barium MCL of 1.0 mg/l. One commenter submitted detailed scientific information on barium, which has been considered by EPA. The majority of commenters felt the barium MCL should be raised to 4.7 mg/l, which is the level the National Academy of Sciences recommended in *Drinking Water and Health*, Vol. 4. These commenters supported this position because an absorption factor of 20 percent was used, even though conservative, rather than 90 percent which was used for the present MCL. These commenters felt that, "there is no evidence in humans that gastrointestinal absorption rates are significantly different for adults or children". They also questioned using the new-born rat as a model for children. Furthermore, they felt that the possible role of barium and cardiovascular disease may not be supported since they are based on intravenous studies.

Six commenters felt that the standard should remain the same, whereas, two commenters felt the standard should be deleted. No reasons were stated for either position.

Cadmium

Twelve commenters addressed the present cadmium MCL of 0.010 mg/l. The majority of commenters felt the MCL should remain the same. One commenter mentioned leaching of cadmium due to corrosion of galvanized pipe as the mode of exposure in drinking water. Two estimates of the relative source contribution of cadmium from drinking water were 10 percent and 6.1 percent. One commenter felt the MCL should be raised but did not specify a level.

Chromium

Twenty-two comments addressed the present MCL for total chromium of 0.05 mg/l. Some commenters submitted detailed scientific information on chromium which has been considered by EPA. The majority of commenters felt the MCL should be changed either by establishing a separate MCL for trivalent (Cr III) and hexavalent chromium (Cr VI) or establishing an MCL for only hexavalent chromium. Their reasoning was that the two valence states can be distinguished analytically and an MCL for Cr(VI) is warranted based on its toxicity while Cr(III) is non-toxic and considered an essential nutrient. This position follows NAS' recommendation in *Drinking Water and Health*, Vol. IV. Two commenters suggested screening for total chromium and when this exceeds the numerical standard, analyzing for hexavalent chromium to determine whether the water meets the standard. These commenters further stated that total chromium in drinking water is not of significant concern. Reasons for this opinion included: (1) Chromium is extremely insoluble and immobile in the natural environment, (2) it is rarely found at concentrations above 0.05 mg/l, (3) only the trivalent form occurs in natural waters since the hexavalent form is quickly reduced, and (4) traces of Cr(VI) would be quickly converted to Cr(III) due to the acidic nature of the stomach. Most of these commenters felt that Cr(III) does not oxidize to Cr(VI) during chlorination. However, one commenter stated that "chlorination will oxidize Cr(III) to Cr(VI) since it is the thermodynamically favored species under oxidative conditions in solution".

A few commenters felt there should be no change to the present MCL for chromium since Cr(III) oxidizes to Cr(VI) and no easy procedure exists to analyze the two species separately.

Two commenters felt that the chromium standard should be deleted altogether. No reasons were stated.

Lead

Twenty-one comments addressed the present MCL for lead of 0.05 mg/l. The majority of commenters felt the present MCL should remain the same since this level protects the health of children and adults. They felt the MCL should not be lowered because the belief that even very low levels of lead in the blood have adverse effects on children is erroneous. Most of these commenters agree with EPA's statement in the ANPRM that, "while lead in drinking water may be the result of contamination of the water source, it most frequently results from corrosion in the distribution system". They favored reducing lead levels by implementing corrosion control programs such as special monitoring activities where corrosion in copper, galvanized and lead piping is suspected of being a problem. Furthermore, they suggested that regulations for corrosion control should be determined by the primary agency based on local conditions. A study in Carroll County, Maryland, found the current MCL was exceeded 24 percent of the time.

Most of the plumbing in this study was copper with lead soldered joints. One commenter noted that cigarettes and alcohol consumption were important sources of lead exposure: 9 percent due to cigarettes, 8 percent due to alcohol, 6 percent due to drinking water, and 77 percent due to other influences.

A number of commenters felt the lead standard should be lowered since "lead is bioaccumulative and the health effects of lead, particularly on the central nervous system is irreversible". Most of these commenters agreed with NAS' recommendation that the MCL should be lowered to 0.025 mg/l. One commenter felt the RMCL should be zero because lead is non-essential and any amount is undesirable and probably harmful and the MCL should be 0.002 mg/l. Another commenter suggested the RMCL should be 0.01 mg/l in order to protect the young and developing nervous systems of infants and young children.

Conversely, one commenter felt the MCL should be raised. No reasons were stated.

Mercury

Eleven comments addressed the present MCL for mercury of 0.002 mg/l. The majority of commenters felt the standard should remain the same and recommended analytical methods be developed to differentiate between organic and inorganic mercury. Conversely, two commenters felt the standard should be deleted. No reasons were given.

Nitrate

Fifteen comments addressed the present nitrate-nitrogen MCL of 10 mg/l. The majority of commenters felt the MCL should remain the same since it is a reasonable standard especially concerning the flexibility afforded for non-community systems. A few other commenters felt that the same provision which applies to non-community water systems should also apply to community water systems since "water related cases of methemoglobinemia that have been reported, have seldom if ever involved community public water systems". Two commenters questioned the nitrate standard because there is little information available to support either retaining or revising the present MCL. They recommended that, "primacy agencies have more flexibility in resolving problems where infants are likely to consume the water". Another commenter stated that nitrate contamination can be minimized by modifying the well construction, as stated in the ANPRM. This information should be disseminated to the consumer.

One commenter believed that the MCL should be raised to 20 mg/l because nitrate is expensive and difficult to remove. They recommended using premixed formula or bottled water and issuing advisories to local physicians, health departments and hospitals, in order to protect children and pregnant women.

Selenium

Eighteen comments addressed the present MCL for selenium of 0.01 mg/l. The majority of commenters felt either the MCL should be raised or deleted. Their reasoning was that selenium has anticarcinogenic potential and the scientific basis for the present MCL appears at best questionable. Also, there is no economical way for small systems to remove selenium at present MCL levels. Conversely, a number of commenters felt the MCL should remain the same and placed in Tier II to allow for monitoring flexibility.

Silver

Eighteen comments addressed the silver MCL of 0.05 mg/l. Some commenters submitted detailed scientific information on silver, which has been considered by EPA. The majority of commenters felt the MCL should be deleted because of minimal occurrence and because of the lack of adverse health effects. A few commenters stated that silver does not occur at elevated levels in drinking water as a result of photographic discharges. Furthermore, "silver is rapidly and almost completely incorporated into sludge during secondary wastewater treatment". Some of these commenters feel that argyria is not an adverse health effect but a cosmetic effect. One commenter cited the MCL reasoning as, "the need to set a standard for silver arises from its intentional addition to water as a disinfectant. The chief effect of silver in the body is cosmetic". They supported NAS' recommendation in *Drinking Water and Health*, Vol. 1 to delete the MCL due to limited occurrence. Some commenters suggested preparing a health advisory for silver.

Five commenters felt there should be no change to the silver MCL. They felt it should be in Tier II allowing the States flexibility in monitoring due to silver's infrequent occurrence.

Aluminum

Twenty-two commenters addressed the possibility of establishing a MCL for aluminum. Three commenters submitted detailed scientific information on aluminum, which has been considered by EPA. The majority of commenters felt aluminum does not warrant an MCL because drinking water is not a significant source of aluminum exposure and there are no clearly demonstrated adverse health effects for the general population. Most of these commenters felt aluminum should be in Tier III so as to protect the sensitive subpopulation of dialysis patients. However, one commenter stated, "normal dietary sources of aluminum are an unlikely source of concern relative to the dementia cited in the ANPRM". Another commenter suggested reporting requirements similar to sodium, on an annual basis to local health officials to afford protection to dialysis patients. Two commenters felt that regulations under the SDWA are not an appropriate vehicle to deal with senile dementia and dialysis encephalopthy. A number of commenters raised the point that, "any limitations placed on aluminum in drinking water should recognize the importance of the use of alum in the treatment of drinking water". These commenters stressed that aluminum salts used in water treatment are the most common source of this metal in drinking water.

Conversely, a few commenters felt that an MCL was justified based on the adverse health effects. One commenter suggested adopting the WHO guideline of 0.2 mg/l.

Antimony

Fourteen comments addressed the possibility of establishing an MCL for antimony. All of the commenters felt that an MCL was not warranted based on lack of occurrence and adverse health effects. A few commenters recommended developing a health advisory for antimony (Tier III).

Asbestos

Twelve commenters addressed the possibility of establishing an MCL for asbestos. All of the commenters felt that an MCL is not justified. One commenter observed that all but a small percentage of U.S. drinking water contains asbestos concentrations below on million fibers per liter. This exposure is due to natural erosion. This commenter stated that exposure to asbestos in food and air is estimated to be 1,000 to 10,000 times that due to drinking water. The above commenters felt that there is no evidence available to demonstrate a health risk from ingested asbestos. One commenter stated that "if there is a causal relationship between asbestos in drinking water and cancer, it is extremely weak". Two commenters stated, "if additional research demonstrates an adverse health effect from ingested asbestos, control can be provided by requiring properly designed and operated filtration plants for surface water supplies and distribution of non-corrosive water". A number of these commenters felt asbestos should be in Tier III.

Beryllium

Six commenters addressed the possibility of establishing an MCL for beryllium and they all agreed that an MCL is not warranted. One commenter stated that there is no evidence that ingested beryllium poses a human cancer risk nor any other adverse health effects. Furthermore, beryllium is present in natural surface waters at concentrations generally less than 1.0 μg/l with average concentrations of generally less than 0.2 μg/l. Beryllium is relatively insoluble and is rapidly absorbed by clays.

Copper

Fifteen comments addressed the possibility of establishing an MCL for copper. The majority of commenters felt an MCL is not warranted and copper should remain as a secondary regulation. A few of these commenters recommended copper be placed in Tier III. Conversely, one commenter felt an MCL should be established because there is evidence of adverse health effects from exposure to elevated levels in a public water supply system in their State.

Cyanide

Eight comments addressed the possibility of establishing an MCL for cyanide in a general fashion. All of the commenters felt that a MCL was not required but recommended a health advisory be set (Tier III).

Molybdenum

Thirteen comments addressed the possibility of establishing an MCL for molybdenum. All of the commenters felt an MCL was not justified due to lack of adverse health effects. One commenter stated that a failure in the ANPRM was the omission of discussing the question of molybdenum deficiency particularly as it relates to cancer. This commenter explained the limitation of NAS' adequate and safe intakes, that it is a range, not a specific limit. A few of the above commenters recommended molybdenum for Tier III.

Nickel

Thirteen comments addressed the possibility of establishing an MCL for nickel. All of the commenters stated that an MCL is not warranted since there are no adverse health effects and nickel in drinking water contributes a very small portion of the daily intake. One commenter stated that it is seldom observed in fresh water.

Sodium

Eighteen comments addressed the possibility of establishing an MCL for sodium. Presently, there are monitoring and reporting requirements for sodium to protect the sensitive subpopulation on sodium restricted diets. All of the commenters stated that an MCL is not required by recommended developing a health advisory (Tier III). These commenters stated that food is the major source of sodium, not drinking water. One commenter noted that drinking water sodium levels seldom exceed 200 mg/l. Another commenter recommended that point-of-use treatment devices are the most practical, effective and economical means for removing sodium. They also suggested that EPA do research on the role of chloride and hypertension. Some treatments add sodium to drinking water, such as soda ash addition and ion exchange softening.

Sulfates

Fourteen comments addressed the possibility of establishing an MCL for sulfates. Presently, there is a secondary maximum contaminant level of 250 mg/l. All of the commenters recommended that an MCL was not warranted and should remain as a secondary regulation since the sole attributable adverse health effect is as a laxative. Two commenters noted that elevated levels of sulfate are not uncommon. Levels as high as 2,000 to 3,000 mg/l have been reported. However, one commenter stated that "EPA's 1975 Interstate Water Carrier Analysis found that even the highest concentration of sulfate detected was below the level at which adverse health effects occur; 96 percent less than, 250 mg/l". This commenter supported NAS' contention that there are no observable adverse health effects at 500 mg/l.

Thallium

Five comments addressed the possibility of establishing an MCL for thallium in a general fashion. All of the commenters felt that an MCL was not warranted; no reasons were stated.

Vanadium

Twelve comments addressed the possibility of establishing an MCL for vanadium. They all felt that an MCL was not justified and that a health advisory should be developed (Tier III). One commenter stated that vanadium is "poorly absorbed when ingested and there is a lack of evidence of any chronic oral toxicity".

Zinc

Seventeen comments addressed the possibility of establishing an MCL for zinc. Presently, there is a secondary maximum contaminant level of 5 mg/l. All of the commenters felt an MCL for zinc was not warranted. Most of the above commenters suggested developing a health advisory (Tier III) and/or maintaining the secondary drinking water regulation. One commenter stated that there is no evidence of chronic zinc toxicity and acute symptoms do not apparently occur in water at levels less than 40 mg/l. Another commenter noted that "at levels well below toxicity, it would cause taste problems making the water unfit to drink".

Synthetic Organic Chemicals (SOCs)

Twenty-two comments addressed the issue as to whether or not to establish RMCLs for synthetic organic chemicals. The majority of comments dealt generally with synthetic organic chemicals, not specific chemicals. Most of the commenters felt that regulations should be set for SOCs and put in Tier II so primacy agencies would have monitoring flexibility to account for wide variations of occurrence. Other commenters recommended developing health advisories (Tier III) until sufficient occurrence and health effects data are available. One commenter noted that the only pesticides likely to intrude into ground water are highly polar, water-soluble, soil-incorporated compounds such as aldicarb, and conditions can be evolved to limit their leaching. A few commenters suggested that a random, nationwide survey should be conducted and funded by EPA to determine the frequency of occurrence and concentration levels to see whether a contaminant is placed in Tier II or III. Another commenter noted that, "the availability of health advisories, in the absence of a drinking water standard help present a more accurate picture of the health issues to the public, however, in many cases, the absence of a drinking water standard may actually result in the installation of treatment facilities for levels of contamination which actually do not exceed the Health Advisory level. Were formal MCLs established, it is unlikely that removal would occur unless the MCL were exceeded". In regard to the six pesticides currently regulated by EPA, one commenter stated that, "there are virtually no cases of non-compliance".

PAHs

Two commenters specifically addressed PAHs. One commenter stated that "the control of PAHs could best be implemented by limiting or discontinuing the use of coal-tar products in water distribution and storage systems. The other commenter recommended PAHs for either Tier II or III due to their widespread use in the water supply industry and their high toxicity.

Acrylamide

Two commenters felt it was inappropriate to establish an MCL for acrylamide. One of the two commenters want the phrase in the ANPRM of "total acrylamide" to be replaced with "acrylamide monomer". They recommended that EPA delay establishing an RMCL for acrylamide

until they complete an oncogenicity/chronic toxicity study. Another commenter stated that "residual acrylamide is regulated by FDA and if this standard does not protect public health, then the FDA standard should be adjusted rather than establishing additional regulations".

Adipates

Two commenters felt that an MCL for adipates was not warranted since there are no ingestion related adverse health effects and results from unpublished data indicate that adipates do not persist in the water column.

Glyphosate

Two commenters did not support an MCL for glyphosate. One commenter was against using registration of a compound for aquatic use as the single determining criterion. "The mere potential for presence in raw water does not of itself present a significant hazard to the public health. Environmental fate, treatability and toxic properties of glyphosate are very favorable and argue against the need for an MCL. Furthermore, analytical methodology is very expensive and requires a high degree of skill."

DBCP

One commenter did not support an MCL for DBCP because the commenter felt that "there are no adverse health effects below 100 ppb and certainly not below 50 ppb. In addition, in humans, there is no increase in tumor formation due to DBCP occupational exposure which is orders of magnitude higher than drinking water exposure". Detailed health effects information was submitted by this commenter, which has been considered by EPA.

Phthalate Esters

Two commenters did not support an MCL for phthalate esters because of limited occurrence and insufficient toxicity to warrant regulation. Also, phthalates are bio-degradable in water.

Alachlor

One commenter did not favor establishing an MCL for alachor because occurrence in drinking water is low.

Xylenes

One commenter did not support an MCL for xylene. No reasons were given.

Toluene

Two commenters felt that an MCL was not warranted for toluene because according to EPA's Health Assessment Document and the Science Advisory Board, "no adverse health effects are likely in humans at current exposures".

Microbials

Total Coliforms

The MCL for total coliforms of <1/100 ml monthly average and 4/100 ml per single sample was addressed by twenty-three comments. A number of issues were raised in the ANPRM, including:

- Is the total coliform test still appropriate as an indicator?
- Is the presence/absence test appropriate?
- Are check samples appropriate?

All of the commenters agreed that the total coliforms test is still an appropriate indicator of the microbiological quality of drinking water and should remain as an MCL. Two of these commenters felt that an RMCL for total coliforms is inappropriate since this is an indicator of water quality, not contaminants per se, but favored a coliform MCL. However, most of these commenters felt the MCL should be simplified. A recommendation supported by many was the presence/absence test. Some commenters noted that the presence/absence test has merit but is not without problems. One commenter stated they "prefer the presence/absence test over estimates of the most probable number; however, the changes in procedures should be accompanied by a requirement to take and test more samples and to conform to other statistical constraints needed to assure that the method is reliable. Furthermore, at times, coliforms and other bacteria remain viable in water, but fail to grow and they are not detectable by standard analytical methods". It should be noted that a few commenters were against using the presence/absence test because there is not enough data to support this test for its use either in conjunction with, or as a substitute for existing procedures.

Another argument for simplifying the present coliforms MCL came from small water supply systems who said that "monthly averages are not only complicated but meaningless for small systems. The significance of the exact number of bacteria is not understood".

Most of the commenters felt that a "check" sample is imperative when a positive coliform sample occurs. A number of these commenters recommended that "check" sample results should be included in calculating compliance, unlike the current practice.

In addition, a few commenters suggested measuring only for fecal coliforms, not total coliforms since it would better reflect the conditions of the water system.

Turbidity

Twenty-two comments addressed the turbidity MCL of 1 turbidity unit (TU) (up to 5 TU). All of the commenters supported inclusion of turbidity in the Revised Regulations to insure the microbiological quality of drinking water. The majority of these commenters recommended turbidity for Tier I and retention of the same level for the MCL. Two commenters states that an RMCL for turbidity is inappropriate since turbidity is an indicator of water quality, not contaminants per se, but favored an MCL. A few commenters recommended either lowering the MCL to 0.2 TU for protection against *Giardia* and other cysts or establish a treatment goal of 0.2 TU as guidance.

Standard Plate Count

Twenty-four comments addressed the possibility of establishing an MCL for standard plate count (SPC). An overwhelming majority felt that an MCL was not warranted for the following reasons:

- A significantly large number of waterborne illnesses are not correlated to bacteria other than those specifically recoginzed as pathogenic,
- SPC is a good operational tool, best used as a guideline or screening mechanism, and
- SPC was recommended to be used in conjunction with the total coliforms test.

Conversely, a few commenters supported establishing an MCL for standard plate count. They recommended an MCL in the range of 100 to 500 colony-forming units (CFU)/ml. Their reasoning was based on the following:

- Confirmation of >500 CFU/ml should cause the water to be non-potable and require treatment,
- In one public water system a good correlation exists between SPC and chlorine residuals. In areas with low to non-existent chlorine residuals, high SPCs are seen although no coliforms are present. The reverse is true in areas with sufficient residual—no coliforms and low SPC, and
- Interference of total coliform analysis.

Giardia

Eighteen comments addressed the possibility of establishing an MCL for *Giardia*. The majority of commenters did not favor establishing an MCL because the analytical methodology is not economically or techically feasible. In addition, a few of these commenters felt *Giardia* does not constitute a significant threat to the general

population. One of the above commenters stated, "efforts should be made to develop improved testing procedures for *Giardia;* if so, then an MCL for *Giardia* should be established".

Some of the commenters who did not favor a drinking water standard for *Giardia,* mentioned that filtration followed by disinfection is effective against *Giardia.* However, they opposed mandatory filtration as the only alternative to protect against *Giardia,* but recommended source control (e.g., beaver removal). One commenter further stated that "filter treatment is neither the cheapest nor the most effective means of control of *Giardia* cysts in drinking water supplies for a required treatment method for Giardiasis control".

Conversely, two commenters felt an MCL should be established even though *Giardia* is difficult to enumerate but rather easy on a presence/absence basis. One commenter stated that, "25% of the cases of waterborne disease reported between 1981–80 were due to *Giardia".* Another commenter felt that *Giardia* should be monitored on a monthly basis for all untreated or disinfected only water supplies. Furthermore, "when an analytical method is available, then an MCL of 0 cysts should be established for finished water regardless of treatment".

The issue of mandatory filtration will be further discussed later in this section.

Viruses

Nineteen comments addressed the possibility of establishing an MCL for viruses. All of the commenters did not favor an MCL for viruses because analytical methods are not available which are timely and cost-effective. They felt more research was needed in this area. Proper disinfection should be emphasized but these commenters did not recommend mandatory disinfection.

Legionella

Eighteen comments addressed the possibility of establishing an MCL for *Legionella.* Every commenter felt that an MCL was not warranted since the relationship beween *Legionella* and public water systems has not been established. One commenter noted that, "an MCL for *Legionella* is not warranted because it is a problem that originates with a user's substandard operation of a hot water system". Another commenter further stated that, the best defense is education of homeowners and building supervisors". In addition, another commenter felt that an MCL was not warranted because the primary route of infection is via the respiratory system, and not enteric. *Legionella* is considerably resistant to chlorination and an MCL would just impose heavy costs with essentially no benefits. One State noted that they have had several *Legionella* outbreaks which have been due to an appurtenance in internal plumbing; therefore, control should be directed to appurtenances rather than through drinking water standards.

(3) Should a treatment technique requirement of disinfection be set for all ground water systems?

Twenty-two comments addressed the possibility of establishing a treatment technique requirement of disinfection for all ground water systems. The majority of commenters opposed mandatory disinfection of ground water systems. They felt that mandatory disinfection is a State discretion issue. Furthermore, these commenters recommend physical protection of the source, periodic sanitary surveys and good well isolation and construction. Most of the above commenters urged EPA to focus its efforts on bacterial standards and not on treatment techniques. One commenter felt that properly sited and constructed ground water systems which are regularly monitored for coliforms will not pose a significant added health risk. One State who strongly opposed mandatory disinfection stated that, "it is politically difficult to accomplish the installation of chlorination equipment on all ground water supplies with even further difficulties anticipated in continuing the treatment once started".

Conversely, some commenters favored mandatory disinfection for all ground water systems. However, a few of these commenters felt that States should be allowed the flexibility to waive for systems based on periodic sanitary surveys and good well construction.

• Should a treatment technique requirement of filtration be set for surface water systems?

Nineteen comments addressed the possibility of establishing a treatment technique requirement of filtration for surface water systems. The majority of commenters favored mandatory filtration for surface water systems to insure the microbiological quality of the drinking water. One commenter felt filtration should be a Tier II standard, with the provision that variances would be allowed if suitable monitoring and watershed characteristics could demonstrate no health risk. A few of these commenters mentioned that mandatory filtration seems prudent particularly in light of the growing concern over infectious agents, such as *Giardia.* One commenter further stated that "the SDWA provides for treatment requirements where monitoring techniques are not practical or available, such as *Giardia,* which can be removed by filtration followed by disinfection". This commenter also supported mandatory disinfection for all public water systems, as a Tier I standard to afford protection against (1) unexpected changes in raw water quality, (2) introduction of contamination in the distribution system, and (3) viruses and *Legionella* which can pass filtration.

The minority opinion who did not favor mandatory filtration for all surface water sytems felt this was a State discretion issue and recommended that it was more appropriate to establish and enforce proper MCLs to insure the microbiological quality of drinking water and then vary monitoring in accordance with the type of source and treatment provided. Furthermore, most of these commenters were against mandatory filtration as the only alternative to protect against *Giardia.* They recommended source control and periodic sanitary surveys. One commenter also recommended "disinfection of surface water supplies and an aggressive monitoring program in the watershed and distribution system," which is consistent with the Microbiology Workshop conclusion, "all surface water sources should be pretreated by such processes as coagulation, sedimentation and filtration or their equivalent prior to disinfection, unless it can be shown on the basis of a sanitary survey that such treatment is not necessary". Another commenter stated that "the establishment of treatment standards other than disinfection is not justified when there are means available to determine water quality".

(4) Is using the ADI an appropriate method for establishing RMCL for non-carcinogens?

Five comments addressed this issue of the ADI approach for non-carcinogens. All of the commenters felt that the ADI approach was quite valuable and appropriate. Two commenters emphasized that the contribution of drinking water to the total exposure should be considered.

(5) What safety factors should be used in conjunction with chronic toxicity data in setting RMCLs for non-carcinogens?

Four commenters addressed the issue of safety factors for non-carcinogens. The commenters recommendations were varied. Two commenters suggested that EPA use a range of factors so that the exact magnitude of uncertainty depends on consideration such as the species tested, and the quality and quantity of

the test data. Another commenter stated that "a safety factor of 100 should be used to account for differing sensitivities within the heterogeneous population (e.g., young vs. old); variability in body weights and the amount of water ingested daily; and uncertanties in extrapolation". Another commenter felt, "NAS" safety factors are appropriate only when epidemiolgical date are lacking. If historical data are available to allow a lower safety factor (e.g., NO_3) or where a benefit can be prescribed (e.g., fluoride) then a lower safety factor should be applied".

(6) What approach should be used to set RMCLs for carcinogens?

Eight commenters addressed how RMCLs should be set for carcinogens. Four commenters felt that setting RMCLs at zero for non-threshold carcinogens was appropriate, however RMCLs must be clearly defined as a health goal. A common sentiment among some of these commenters was that zero provides little foundation for the establishment of MCLs. Furthermore, these commenters felt that RMCLs serve no purpose and are impractical because they are confusing to the public and the press, if not the regulated community. Despite the shortcomings of RMCLs, a few commenters made recommendations on how to improve the understanding of RMCLs. One commenter recommended that EPA, States and the American Water Works Association develop educational material to explain the differences between RMCLs and MCLs. Another commenter suggested that RMCLs and MCLs should be proposed and promulgated simultaneously.

Another suggestion as to how RMCLs should be set for carcinogens was expressed by one commenter to, "evaluate each compound and based on strength of the scientific data and comparative carcinogenicity of each compound, establish an RMCL at a level determined to have a mininal or insignificant health risk. These risk levels should be consistent with past determinations of "acceptable" risks to society, possibly 10^{-6}".

Two commenters were opposed to using risk models because there are such a variety of models which argue against the selection of only one for risk assessments. One commenter suggested EPA should consider a combination of mathematical models and the safety factor approach. Another commenter said, "due to the inadequacies in today's science, EPA should state that they are unable to determine safe levels for carcinogens".

One commenter recommended that animal bioassay results would have to be considered "sufficient" evidence of carcinogenicity before they can be considered for use in human cancer risk. They suggested using IARC's classification scheme which states that "limited" evidence in animals is "inadequate" to evaluate the carcinogenicity in humans.

(7) Is waiving certain MCLs when susceptible populations are not affected an appropriate approach?

Five comments addressed the issue whether to waiver certain MCLs when susceptible populations are not affected. The commenters were split on this issue, three felt this was an appropriate approach, particularly concerning nitrate.

Two commenters did not favor this approach. One commenter stated that, "waivers based on population would be very subjective and lead to the setting of undersirable precedents. Gathering the data to make determinations for a 'susceptible population' would be too timely and costly and populations are too mobile. Furthermore, failing to account for synergistic effects from other exposures would make any waiver meaningless in terms of protecting public health".

(8) Should separate or different MCLs be considered for certain contaminants for non-community water systems?

Two commenters addressed this issue. One commenter favored the existing procedures for non-community water systems to comply with the MCLs for coliforms, turbidity and nitrates. The other commenter recommended "changing the definitions for community and non-community to more properly reflect the difference between transient and non-transient populations because the current approach of resident vs. non-resident does not properly protect the health of persons using drinking water from systems such as schools and factories which are non-community systems that may have excessive concentrations of other contaminants, such as lead. Community systems should apply to non-transient populations such as schools, day-care facilities, and factories not just residential. Non-community systems should apply to true transient populations such as hotels, campgrounds, gas stations, restaurants, etc".

(9) Which analytical methods are most reliable?

Only a few comments were received which addressed the availability of analytical methods for contaminants under consideration. The following discussion will be summarized per chemical.

Inorganic Chemicals

Asbestos

One commenter noted that the only available analytical method for asbestos in water, transmission electron microscopy, is very expensive ($300–$600 per sample). This method is neither precise nor accurate enough to use for enforcement purposes.

Chromium

One commenter noted that there are two methods to separate dissolved Cr (III) from Cr (IV). The first was developed by Martin and Riley at U.S. EPA, Environmental Monitoring and Support Laboratory (EMSL). The colorimetric method [*Standard Methods*, 15th ed. #312.B) is also valuable for distinguishing the hexavalent form. They also mentioned that Krull, Panaro and Gersmar (*J. Chrom. Science*, In press, 1983) have developed a method for speciation of Cr (VI) and Cr (III) in water using HPLC-Direct Coupled Plasma Emission Spectroscopy.

Another commenter recommended that the Atomic Absorption method be used to screen for total chromium, but that Cr (VI) should be the basis for the MCL.

Pesticides

One commenter noted the analytical method for glyphosate in water requires a high degree of technical skill and is very expensive. Costs are about $200 per sample. National cost for each public water system to monitor two times per year would approach $100 million.

Another commenter noted that while electron capture detection has excellent characteristics for insecticides and herbicides regulated by the SDWA, it has generally poor detection ability for the currently used phosphorous and nitrogen containing pesticides. Specific detectors are required such as, thermionic detection to detect even high levels of atrazine, simazine and tabufos.

PART 141—[AMENDED]

For the reasons set out in the preamble, it is proposed that the following be added to proposed Subpart F, Part 141, Subchapter D, Chapter I of Title 40, *Code of Federal Regulations* as proposed on May 14, 1985 (50 FR 20175).

1. The authority section of Part 141 continues to read as follows:

Authority: 42 U.S.C. 300g–1, 300g–3, 300j–4, and 300j–9.

2. It is proposed that Subpart F, 40 CFR 141.50 is amended by adding (a) (6) through (15) and (b) table entries (4) through (18) to read as follows:

§ 141.50 Recommended maximum contaminant levels for organic contaminants.

(a) * * *

* * * * * *

(6) Acrylamide,
(7) Alachlor,
(8) Chlordane,
(9) DBCP,
(10) EDB,
(11) Epichlorohydrin,
(12) Heptachlor,
(13) Heptachlor epoxide,
(14) PCBs,
(15) Toxaphene.

(b) * * *

Contaminant	RMCL in mg/l
* * * * *	*
(4) Aldicarb, aldicarb sulfoxide and aldicarb sulfone	0.009
(5) Carbofuran	0.036
(6) 2,4-D	0.07
(7) o-Dichlorobenzene	0.62
(8) cis-1,2-Dichloroethylene	0.07
(9) trans-1,2-Dichloroethylene	0.07
(10) Ethylbenzene	0.68
(11) Lindane	0.0002
(12) Methoxychlor	0.34
(13) Monochlorobenzene	0.06
(14) Pentachlorophenol	0.22
(15) Styrene	0.14
(16) Toluene	2.0
(17) 2,4,5-TP	0.052
(18) Xylene	0.44

3. It is proposed that proposed Subpart F, § 141.51 be amended by adding (b) table entries (2) through (12) to read as follows:

§ 141.51 Recommended maximum contaminant levels for inorganic contaminants

(a) [Reserved]

(b) * * *

Contaminant	RMCL in mg/l
* * * * *	*
(2) Arsenic	0.05
(3) Asbestos (medium and long fibers)	[1]7.1
(4) Barium	1.5
(5) Cadmium	0.005
(6) Chromium (total)	0.12
(7) Copper	1.3
(8) Lead	0.020
(9) Mercury	0.003
(10) Nitrate (as N)	10.0
(11) Nitrite (as N)	1.0
(12) Selenium	0.045

[1] Million fibers per liter.

4. It is proposed to add a new § 141.52 to 40 CFR Part 141 to read as follows:

§ 141.52 Recommended maximum contaminant levels for microbial contaminants.

(a) Recommended maximum contaminant levels are zero for the following microorganisms: total coliforms, *Giardia,* and viruses.

(b) Recommended maximum contaminant levels for the following microorganisms parameters are as indicated: Turbidity 0.1 Nephelometric Turbidity Unit.

[FR Doc. 85-26417 Filed 11-12-85; 8:45 am]
BILLING CODE 6560-50-M

Federal Register

Wednesday
November 13, 1985

Part V

Environmental Protection Agency

40 CFR Part 141

National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals; Notice of Availability of New Evidence and Request for Comments; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[OW-FRL-2915-6]

National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of new evidence and request for comment.

SUMMARY: This action under the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*) reopens the public comment period for 45 days to provide the opportunity for review and comment on a new report on the toxicology of tetrachloroethylene from the National Toxicology Program. EPA proposed an RMCL for tetrachloroethylene on June 12, 1984 (49 FR 24330) at a level of zero on the basis of limited evidence of carcinogenicity of tetrachloroethylene.

The National Toxicology Program Technical Report is entitled, "Report on the Toxicology and Carcinogenesis Studies of Tetrachloroethylene in Rats and Mice," Board Draft, August 1985. EPA has been informed that the draft has been evaluated by the NTP Board and that one conclusion of the document has been revised as follows: The chemical has been determined to present "clear" evidence of carcinogenicity in rats, rather than "some" evidence.

EPA requests comments on the National Toxicology Program Report. The Agency also requests comments on the classification of tetrachloroethylene as a carcinogen under EPA's carcinogen assessment scheme, as discussed in Section IV of the Final Rule for RMCLs for VOCs, published elsewhere in today's issue. Comments are not solicited on other topics.

DATES: Comments must be submitted by December 30, 1985.

ADDRESSES: Comments should be sent to Comment Clerk, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. If there is significant interest, a public meeting will be held, and separately noticed in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, telephone (202) 382-7575.

SUPPLEMENTARY INFORMATION: The NTP report is available for inspection at EPA, Room 2904 (rear) 401 M St., SW., Washington, DC and at the Drinking Water Supply Branches in EPA's Regional Offices.

I. JFK Federal Bldg., Boston, MA 02203, Phone: (617) 223-6486, Jerome Healy

II. 26 Federal Plaza, Room 824, New York, NY 10278, Phone: (212) 264-1800, Walter Andrews

III. 6th & Walnut Sts., Philadelphia, PA 19106, Phone: (215) 597-9873

IV. 345 Courtland Street, Atlanta, GA 30365, Phone: (404) 881-3781, Robert Jourdan

V. 230 S. Dearborn St., Chicago, IL 60604, Phone: (312) 886-6176, Joseph Harrison

VI. 1201 Elm St., Dallas, TX 75270, Phone: (214) 767-2620, James Graham

VII. 726 Minnesota Ave., Kansas City, KS 66101, Phone: (913) 236-2815, Gerald R. Foree

VIII. 1860 Lincoln St., Denver, CO 80295, Phone: (303) 293-1426, Marc Alston

IX. 215 Fremont St., San Francisco, CA 94105, Phone: (415) 974-8076, Leslie Ragle

X. 1200 Sixth Ave., Seattle, WA 98101, Phone: (206) 442-1225, Jerry Opatz

A limited number of copies of the NTP report are available from NTP Public Information Office (MDB 2-04), National Toxicology Program, P.O. Box 12233, Research Triangle Park, North Carolina 27709 (919-541/3780). The report is also available for sale from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (703/487-4650).

Dated: October 10, 1985.

Lee Thomas,

Administrator.

[FR Doc. 85-26418 Filed 11-12-85; 8:45 am]

BILLING CODE 6560-50-M

Reader Aids

Federal Register

Vol. 50, No. 219

Wednesday, November 13, 1985

INFORMATION AND ASSISTANCE

SUBSCRIPTIONS AND ORDERS

Subscriptions (public)	202-783-3238
Problems with subscriptions	275-3054
Subscriptions (Federal agencies)	523-5240
Single copies, back copies of FR	783-3238
Magnetic tapes of FR, CFR volumes	275-2867
Public laws (Slip laws)	275-3030

PUBLICATIONS AND SERVICES

Daily Federal Register

General information, index, and finding aids	523-5227
Public inspection desk	523-5215
Corrections	523-5237
Document drafting information	523-5237
Legal staff	523-4534
Machine readable documents, specifications	523-3408

Code of Federal Regulations

General information, index, and finding aids	523-5227
Printing schedules and pricing information	523-3419

Laws 523-5230

Presidential Documents

Executive orders and proclamations	523-5230
Public Papers of the President	523-5230
Weekly Compilation of Presidential Documents	523-5230

United States Government Manual 523-5230

Other Services

Library	523-4986
Privacy Act Compilation	523-4534
TDD for the deaf	523-5229

FEDERAL REGISTER PAGES AND DATES, NOVEMBER

45591-45804.....1
45805-45900.....4
45901-45984.....5
45985-46278.....6
46279-46414.....7
46415-46626.....8
46627-46736.....12
46737-47026.....13

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamation:
5402.....45591
5403.....45593
5404.....46279
5405.....46737
Executive Orders:
12170 See Notice of November 1, 1985.....45901
Administrative Orders:
Notices:
November 1, 1985.....45901

7 CFR

29.....45805, 45806
404.....45903
405.....45903
408.....45903
442.....45903
999.....45807
1002.....45595
1004.....45595
1032.....46627
1772.....46628
1864.....45740
1872.....45740
1900.....45740, 45906
1910.....45740
1924.....45740
1941.....45740
1943.....45740
1945.....45740
1950.....45740
1951.....45740
1955.....45740
1960.....45740
1962.....45740
1965.....46415
1980.....46415
Proposed Rules:
70.....45829
225.....45898
400.....45625
426.....46772
928.....46773
989.....45627
1007.....46441

8 CFR

100.....45597
Proposed Rules:
204.....46441

9 CFR

71.....45985
78.....45808, 45985
112.....46416
Proposed Rules:
51.....46077
75.....46079
92.....45918
94.....46443

10 CFR

Ch. I.....45597
20.....46630
21.....46630
73.....46630
Proposed Rules:
Ch. I.....46672
19.....45628
21.....45628
30.....45628
40.....45628
50.....45628
70.....45628
71.....45628
73.....45628
110.....45628
962.....45736
1046.....46672

12 CFR

265.....45809
561.....46739
563.....45988, 46739
591.....46744
611.....46417
615.....46418

13 CFR

121.....46418
309.....46749

14 CFR

21.....46872
23.....46872
39.....45598, 45810, 46631, 46750
71.....45718, 45810, 45989, 46281, 46751, 46753
91.....45599, 46872
97.....46421
Proposed Rules:
39.....45829, 46444, 46775-46777
71.....45830, 46447-46452
139.....46673

15 CFR

923.....46422
930.....46422

16 CFR

13.....45990, 46423, 46753, 46757
803.....46633
Proposed Rules:
13.....46453
259.....46300
444.....46082
453.....46266-46271
1500.....46300

17 CFR

33 45811
200 ..... 45602, 45990
249 46281
275 46281

Proposed Rules:

1 ..... 45831, 46674
33 ..... 45831, 46674
145 45833
146 45833
190 ..... 45831, 46674
240 46731

18 CFR

2 45907
157 45907
250 45907
271 46758
284 ..... 45907-45908, 46424
375 45907

19 CFR

175 45812

Proposed Rules:

191 45919

20 CFR

416 46760

Proposed Rules:

416 46778

21 CFR

73 ..... 45814, 45991
74 45909
81 45909
82 45909
310 46582
436 45603
522 45603
558 ..... 45910, 46282
1020 46646
1308 45815

Proposed Rules:

343 46588
355 46303
357 46594

22 CFR

Proposed Rules:

41 46085
42 46085
60 46555
61 46555
62 46555
63 46555
64 46555
65 46555

23 CFR

635 46282
658 46425
1204 45815

24 CFR

20 45910
201 45993
203 45993
234 45993
251 46763

25 CFR

61 46427

26 CFR

1 ..... 45996, 46004, 46006
5 45996
5h 45996
602 ..... 45996, 46004, 46006

Proposed Rules:

1 ..... 46086-46088, 46303, 46306, 46460, 46674
20 46460
25 46460
53 46460
602 ..... 46088, 46460

27 CFR

47 46647

28 CFR

2 46282
17 46388

29 CFR

Proposed Rules:

1953 ..... 46460, 46462

30 CFR

938 45820

31 CFR

103 46283
355 46284
545 46726

32 CFR

706 46435

33 CFR

117 46647
165 46284

Proposed Rules:

117 46674
165 46780

34 CFR

Proposed Rules:

614 46675

36 CFR

254 45823
327 46284
902 ..... 45823, 45824
903 45824
905 45824
907 45824
908 45824

Proposed Rules:

903 45841

38 CFR

21 46763

Proposed Rules:

21 45629

39 CFR

Proposed Rules:

10 ..... 46307, 46463
310 46464
320 46464

40 CFR

35 ..... 45892, 46648
52 ..... 45603, 45606, 46041
60 46042
61 ..... 46042, 46284
81 ..... 46436, 46649, 46650
141 46880
158 46764
162 46764
180 ..... 45607, 46043
271 46437
280 46602
716 46295
717 46766

Proposed Rules:

52 ..... 45630, 46782
60 46464
65 46307
81 ..... 45630, 46089
141 46902-47025
142 46902
180 46103
261 46468
271 46734
302 46468
435 46784
439 45920
704 ..... 46090, 46309
716 ..... 46104, 46309
796 46785
798 ..... 46104, 46121
799 ..... 46909, 46104, 46121, 46133, 46785

42 CFR

412 46651
432 46652
433 46652
435 46652
436 46652

Proposed Rules:

442 45921

43 CFR

1820 46044
4100 45824
2780 46770

44 CFR

64 46297
65 46044
67 46045

Proposed Rules:

67 46143

45 CFR

801 45608

46 CFR

Proposed Rules:

172 46315

47 CFR

1 45608
13 45827
73 46047
90 46048
97 46048

Proposed Rules:

Ch. 1 45841
15 45843
18 46144
21 45608
22 45843
76 45843

48 CFR

Ch. 24 46572
319 46298

Proposed Rules:

31 ..... 45708, 46470
235 46796

49 CFR

Ch. V 46666
1 ..... 49614, 45728
106 45728
107 45728
171 45728
172 ..... 45728, 46053
173 ..... 45728, 46053-46054
174 ..... 45728, 46053
175 45728
176 ..... 45728, 46053
177 45728
178 45728
190 45728
191 45728
192 45728
193 45728
195 45728
571 46056
1144 46066

Proposed Rules:

192 45845
212 45917
217 45917
218 45917
219 45917
225 45917
571 46144

50 CFR

17 45614-45621
204 46068
285 45828
650 46069
652 ..... 46072, 46671
663 45828
675 46072

Proposed Rules:

17 ..... 45632-45638, 45846, 46320, 46797
652 46145

LIST OF PUBLIC LAWS

Last List November 8, 1985

This is a continuing list of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone 202-275-3030).

H.J. Res. 126 / Public Law 99-143

To designate the week of November 3, 1985, through November 9, 1985, as "National Drug Abuse Education Week". (November 7, 1985; 99 Stat. 581; 1 page) Price: $1.00