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52 FR 25690

ENVIRONMENTAL PROTECTION AGENCY

AGENCY: Environmental Protection Agency (EPA).

40 CFR Parts 141 and 142

National Primary Drinking Water Regulations; Synthetic Organic Chemicals; Monitoring for Unregulated Contaminants

[WH-FRL-3213-8]

52 FR 25690

July 8, 1987

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ACTION: Final Rule.

SUMMARY: In this notice, EPA is promulgating National Primary Drinking Water Regulations (NPDWRs) for certain volatile synthetic organic chemicals (VOCs). Specifically, this notice promulgates maximum contaminant levels (MCLs) for: Trichloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and para-dichlorobenzene. The NPDWRs also include monitoring, reporting and public notification requirements for these eight VOCs. EPA is also publishing the maximum contaminant level goal (MCLG) for para-dichlorobenzene. This notice specifies the best available technology (BAT) upon which the MCLs are based and BAT for the purpose of issuing variances. In this notice, the Agency is also promulgating procedures by which systems may obtain variances and exemptions from these NPDWRs. In addition to the NPDWRs for the eight VOCs, the Agency is also promulgating monitoring requirements for 51 other synthetic organic chemicals which are not regulated by NPDWRs.

EPA proposed NPDWRs, including MCLs, for the eight VOCs listed above on November 13, 1985 (50 FR 46902). New data on the toxicology of para-dichlorobenzene became available after the November 13 notice which changed its health effects classification. EPA proposed to amend the MCLG and repropoed the MCL for this contaminant on April 17, 1987 (52 FR 12876), based on this new information.

EFFECTIVE DATES: This regulation is effective January 9, 1989, except for §§ 141.24(g), 141.35, and 141.40. The information collection requirements in 40 CFR 141.24(g), 141.35, and 141.40 are effective January 1, 1988, if the information collection request is clear by the Office of Management and Budget (OMB) and an OMB clearance number is assigned prior to that date. If not, the requirements will be effective when OMB clears the request and a notice is published. In accordance with 40 CFR 23.7, this regulation shall be considered final agency

action for the purposes of judicial review at 1:00 pm eastern daylight savings time on July 22, 1987.

ADDRESSES: Public comments on the proposal, major supporting documents, and a copy of the index to the public docket for this rulemaking are available for review during normal business hours at the EPA, Room 2904 (rear) in the Public Information Reference Unit, 401 M Street, SW., Washington, DC 20460. A complete copy of the public docket is available for inspection at EPA in Washington, DC by appointment by contacting Ms. Colleen Campbell 202/382-3027.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202/382-7575, or one of the EPA Regional Office contacts listed in "Supplementary Information". Information may also be obtained from the EPA Drinking Water Hotline. The toll-free number is 800/426-4791 and the Washington, DC number is 382-5533.

TEXT:

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Abbreviations Used in This Notice

BAT: Best Available Technology

BTGA: Best Technology Generally Available

CWS: Community Water System

EMSL: EPA Environmental Monitoring and Support Laboratory (Cincinnati)

GAC: Granular Activated Carbon

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LOQ: Limit of Quantitation

MCL: Maximum Contaminant Level (expressed as mg/l) *

MCLG: Maximum Contaminant Level Goal

MDL: Method Detection Limit

mgd: Million Gallons per Day

NIPDWR: National Interim Primary Drinking Water Regulation

NPDWR: National Primary Drinking Water Regulation

NTNCWS: Non-transient Non-community Water System

p-dcb: para-Dichlorobenzene

POE: Point-of-Entry Technologies

POU: Point-of-Use Technologies

PQL: Practical Quantitation Level

PTA: Packed Tower Aeration

PWS: Public Water System

PWSS: Public Water System Supervision

RMCL: Recommended Maximum Contaminant Level

SDWA: Safe Drinking Water Act, or the "Act," as amended in 1986

THMs: Trihalomethanes

URTH: Unreasonable Risk to Health

VOC: Volatile Synthetic Organic Chemical

* 1,000 micrograms (ug) = 1 milligram (mg)

Table of Contents

I. Summary of Today's Actions

II. Background

A. Statutory Authority

B. Regulatory Background

C. Public Comments on the Proposal

III. Explanation of Today's Actions

A. Non-transient Non-community Water System

CLW

0000001588

- B. MCLG for para-dichlorobenzene
 - C. MCLs for VOCs
 - 1. Treatment Technologies
 - 2. Costs
 - 3. Other Factors
 - 4. Summary of MCL Determinations
 - D. Other Treatment Technologies
 - E. Analytical Methods and Compliance Monitoring Requirements
 - 1. Analytical methods
 - 2. Compliance Monitoring Requirements
 - F. Laboratory Approval
 - G. Variances and Exemptions
 - 1. Variances
 - 2. Exemptions
 - 3. Central Treatment vs. POU/Bottled Water
 - H. Public Notification
 - I. Reporting Requirements
 - J. Total Volatile Synthetic Organic Chemicals (TVOC)
 - K. Monitoring for Unregulated Contaminants
- IV. Effective Dates
- V. Impact Analyses
- VI. References and Public Docket

List of Tables

Table 1 -- Final MCLGs and Proposed and Final MCLs for the VOCs

Table 2 -- An Example of Upper Bound Lifetime Cancer Risk (10^{-5}) Estimates for VOCs Categorized as Known or Probable Human Carcinogens

Table 3 -- Schedule of Repeat Monitoring Requirements

Table 4 -- Analyses within the Acceptance Limits of Eleven VOC Samples

Table 5 -- Estimated Costs of Removing VOCs from Drinking Water Using Packed Tower

CLW

0000001589

Aeration or Granular Activated Carbon for the Smallest System Size

Table 6 -- Unregulated Contaminants

Table 7 -- Costs (\$ million/year) for Monitoring for Compliance with MCLs for VOCs and for Unregulated VOCs.

I. Summary of Today's Action

Applicability

The requirements of this notice apply to all community water systems (CWS) and non-transient non-community water systems (NTNCWS).

Non-transient non-community water systems are those which regularly serve the same 25 or more persons at least 6 months per year.

Final MCLG:

para-dichlorobenzene -- 0.075 mg/l

Final MCLs:

- 1. benzene -- 0.005 mg/l
- 2. carbon tetrachloride -- 0.005 mg/l
- 3. 1, 2-dichloroethane -- 0.005 mg/l
- 4. trichloroethylene -- 0.005 mg/l
- 5. para-dichlorobenzene -- 0.075 mg/l
- 6. 1,1-dichloroethylene -- 0.007 mg/l
- 7. 1,1,1-trichloroethane -- 0.20 mg/l
- 8. vinyl chloride -- 0.002 mg/l

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BAT under Section 1412 of the SDWA (MCLs):

Packed tower aeration (PTA) or granular activated carbon (GAC) for all regulated VOCs, except vinyl chloride.

PTA for vinyl chloride.

Other effective removal technologies that treat all of the drinking water in a public supply although not designated BAT may also be applied to achieve compliance.

BAT under Section 1415 (Variances):

Same technologies are BAT as those under Section 1412.

Monitoring Requirements and Compliance Determination

The basic monitoring requirements are as follows:

Quarterly samples for each ground and surface water source.

Composite samples of up to five sources are allowed.

Monitoring requirements are phased in by system size (i.e., population served)

Population served	Monitoring must begin by
>10,000	Jan. 1, 1988.
3,300-10,000	Jan. 1, 1989.
<3,300	Jan. 1, 1991

Determination of compliance is established as follows: Both ground and surface water systems must calculate a running average of the concentration of each VOC, over one year, taking at least one sample per quarter, for each source.

All samples must be used.

For ground waters, the State as primacy agent may reduce the sampling frequency if regulated VOCs are not detected in the first sample. The minimum possible monitoring requirement for compliance is one sample per source.

Repeat monitoring varies from quarterly to once per five years. States determine repeat monitoring requirements based on: (1) Whether or not VOCs have been detected in the initial sampling, and (2) the vulnerability of the system to contamination (determined by the State).

Analytical Methods:

1. EPA Method 502.1 -- Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography.
2. EPA Method 502.2 -- Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography with Photoionization and Electrolytic Conductors in Series.
3. EPA Method 503.1 -- Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography.
4. EPA Method 504 -- 1,2-Dibromoethane and 1,2-Dibromo-3-chloropropane in Water by Microextraction and Gas Chromatography.
5. EPA Method 524.1 -- Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry.
6. EPA Method 524.2 -- Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry.

Laboratory Certification Criteria

Vinyl Chloride:

+/- 40 percent at any concentration

All others:

+/- 20 percent \geq 0.010 mg/l

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+/- 40 percent < 0.010 mg/l

Point-of Entry Devices (POE), Point-of-Use Devices (POU), and Bottled Water

POE may be used to achieve compliance with MCLs; however, POE is not BAT.

POU and bottled water cannot be used to achieve compliance with the MCLs; however, either may, at State discretion, be a condition of granting a variance or exemption.

Variations and Exemptions

Prior to issuing a variance or exemption, the State has the authority to require the public water system to implement additional interim control measures if an unreasonable risk to health exists; among other mitigation techniques, States may require installation of point-of-use devices or distribution of bottled water to each customer as measures to reduce the health risk before granting a variance or exemption.

Monitoring for Unregulated Contaminants

One sample per source is required every five years.

Systems sample according to the procedures and schedules established for VOC compliance monitoring.

Monitoring for the 50 unregulated contaminants is as specified below:

List 1: monitoring required for all systems (34 contaminants).

List 2: monitoring required for vulnerable systems (2 contaminants).

List 3: monitoring required at State discretion (15 contaminants).

Repeat monitoring frequency: Every five years.

EPA will specify a new list before repeat monitoring is required (within five years).

II. Background

A. Statutory Authority

Section 1412 of the Safe Drinking Water Act, as amended in 1986 ("SDWA" or "the Act"), requires EPA to publish Maximum Contaminant Level Goals (MCLGs) and promulgate National Primary Drinking Water Regulations (NPDWRs) for contaminants in drinking water which may cause any adverse effect on the health of persons and which are known or anticipated to occur in public water systems. Under Section 1401, the NPDWRs are to include Maximum Contaminant Levels (MCLs) and "criteria and procedures to assure a supply of drinking water which dependably complies" with such MCLs. Under Section 1412(b)(7)(A), if it is not economically or technically feasible to ascertain the level of a contaminant in drinking water, EPA may require the use of a treatment technique instead of an MCL.

1. MCLs, MCLGs, and BAT

EPA is to establish MCLGs at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety. MCLGs are nonenforceable health goals. EPA published MCLGs, previously called Recommended Maximum Contaminant Levels (RMCLs), for trichloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and para-

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dichlorobenzene on November 13, 1985. The Agency repropoed the MCLG for p-DCB on April 17, 1987 (52 FR 12876), based on new health assessment data.

MCLs are enforceable standards which the Act directs EPA to set as close to the MCLGs as feasible. "Feasible" means feasible with the use of the best technology, treatment techniques, or other means which the Administrator finds available (taking cost into consideration) after examination for efficacy under field conditions and not solely under laboratory conditions. Also, the SDWA requires the Agency to identify the best available technology (BAT) which is feasible for meeting the MCL for each contaminant. NPDWRs are to be amended whenever changes in technology or other means permit greater protection of the health of persons, and the regulations are to be reviewed no less frequently than every three years.

2. Variances and Exemptions

Section 1415 authorizes the State (the term "State" is used in this Preamble to mean the State agency with primary enforcement responsibility for the public water supply system program, or "primacy," or EPA if the State does not have primacy) to issue variances from NPDWRs. The State may issue a variance if it determines that a system cannot comply with an MCL despite application of the best available technology (BAT). Under Section 1415, EPA must propose and promulgate its finding of the best technology, treatment techniques, or other means available for each contaminant (BAT), for purposes of Section 1415 variances, at the same time that it proposes and promulgates a maximum contaminant level for each such contaminant. EPA's finding of best technology, treatment techniques, or other means available for purposes of issuing variances may vary among systems, depending upon the number of persons served by the system or for other physical conditions related to engineering feasibility and costs of complying with MCLs, as considered appropriate by EPA. The State may not issue a variance where an unreasonable risk to health exists. When a State grants a variance, it must at the same time prescribe a schedule for (1) compliance with the NPDWR and (2) implementation of such additional control measures as the State may require.

Under section 1416(a), the State may exempt a public water system from any MCL or treatment technique requirement if it finds that (1) due to compelling factors (which may include economic factors), the system is unable to comply, (2) the system was in operation on the effective date of the MCL or treatment technique, or, for a newer system, that no reasonable alternative source of drinking water is available to that system, and (3) the exemption will not result in an unreasonable risk to health. Under section 1416(b), at the same time it grants an exemption, the State is to prescribe a compliance schedule and a schedule for implementation of any required interim control measures. For exemptions from a NPDWR promulgated after enactment of the SDWA amendments, such as the NPDWRs for the VOCs promulgated in this notice, the compliance date must be no later than 12 months after the date of issuance of the exemption. However, the State may extend the final compliance date for a period not to exceed three years after the date of issuance of the exemption if the public water system establishes that it is taking all reasonable steps to meet the standard once: (1) the system cannot meet the standard without capital improvements which cannot be completed within the period of such exemptions; (2) in the case of a system which needs financial assistance for the necessary improvements, the system has entered into an agreement to obtain such financial assistance; or (3) the system has entered into an enforceable agreement to become part of a regional public water system. For systems that serve 500 or fewer service connections and which need financial assistance to come into compliance, the State may renew the exemption for additional two-year periods if the system is taking all practicable steps to meet the requirements in the previous sentence.

3. Primacy.

Today's regulation is one of many which EPA will promulgate during the next few years, as required by the 1986 Amendments. To retain primary enforcement responsibility ("primacy")

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for the public water system supervision program, States must revise their programs to include regulations that are no less stringent than the Federal NPDWRs, as required by Section 1413 of the Act, EPA plans to amend the Public Water System Supervision (PWSS) Program Implementation regulations, 40 CFR Part 142, to set out the requirements for these program revisions. The amendments will be based on the recommendations of an EPA workgroup which is currently reviewing the issues associated with such requirements. However, since these VOC regulations, promulgated under the authority of Section 1412, go into effect 18 months from the date of this notice, States must begin to modify their programs immediately without waiting for the amendments to 40 CFR Part 142.

The 18-month interval derives from Section 1412(b)(10) of the SDWA which requires that all NPDWRs be in effect no later than 18 months after the promulgation date. EPA takes the position, therefore, that the Federal NPDWRs directly apply to public water systems regardless of whether a State with primacy has adopted the requirements. As such, EPA has some discretion in establishing when States adopt the NPDWRs promulgated in today's notice since the Federal regulations will apply to all systems, even in States with primacy that have not adopted equivalent requirements.

EPA wishes, however, to avoid States having "split" or "partial" primacy, i.e., authority to implement and enforce only part of the PWSS program, for more than a short time. As such, EPA expects primacy States, to the maximum extent possible, to adopt State requirements as stringent as those contained in this Federal regulation within 18 months. Splitting oversight responsibilities, however briefly, will confuse public water system owners and operators as they try to determine which State and Federal regulations apply to them. In addition, EPA implementation and enforcement of regulations that States with primacy have not yet adopted will be limited since the EPA Regional Offices are not currently set up, or funded, to implement a day-to-day operational program. EPA believes that States should operate the total PWSS program, including the changes contained in any new regulations, from the effective date onward.

As the monitoring requirements of this regulation go into effect sooner than eighteen months after publication i.e., January 1, 1988, States with primacy should inform systems under their jurisdiction of their responsibilities under Federal law and ensure that they are monitoring even though the State may not yet have its requirements in place. Further, States should collect and manage the analytical results during this interim period as though they had incorporated the program revisions. States should forward information on violations of the Federal requirements to the applicable EPA Regional Office.

As mentioned in the first paragraph of this section, EPA plans to specify, as part of the revisions to 40 CFR Part 142, the materials States are to submit to EPA so the Agency can determine whether a State has adopted requirements that are no less stringent than the Federal NPDWRs. State program revisions that occur before changes to 40 CFR Part 142 are promulgated must, however, be reviewed by EPA as well. States must demonstrate to EPA that their program revisions allow them to continue to meet the requirements of section 1413 (a) of the SDWA and 40 CFR 142.10 of the Implementation regulations. For example, EPA must review the State's implementing statutory and regulatory changes. It may be necessary in some instances for States to provide a State Attorney General's opinion specifically explaining how the State's statutes and regulations give it the authority to implement and enforce the new requirements. Specific to the program revisions contained in today's Federal notice, States must also provide their methodology for determining the vulnerability of a public water system as this is an integral part of determining the public water system monitoring requirements. States should provide this information to EPA through the applicable EPA Regional Office. To ensure consistency with Federal requirements, EPA encourages States to involve the Regional Offices during the developmental stages of any new statutes or regulations rather than waiting until after final adoption. **CLW**

It is important that public water systems be aware of their responsibilities under the Federal

regulations. Systems in States without primacy are subject to the Federal requirements on the effective date of the NPDWRs, i.e., 18 months from publication in the Federal Register (except for monitoring requirements which are effective January 1, 1988). Public water systems located in States which do not have primacy shall forward all analytical results and other information required by this regulation to EPA directly.

Systems located in States which have primacy, but have not adopted the requirements contained in this regulation, must comply with Federal requirements. Failure by a State with primacy to establish its own requirements does not exempt a system from the Federal requirements and systems which violate a Federal requirement contained in this regulation will be subject to Federal enforcement. Public water systems located in States with primacy should, however, report analytical results and all other information required by this regulation to the State even if the State has not yet adopted the requirements of the regulation. It will be the responsibility of the State, in such cases, to forward information to EPA.

4. Monitoring, Quality Control, and Records

Under section 1401(1)(D) of the Act, NPDWRs 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 that, "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." Section 1445 also requires EPA to promulgate regulations requiring every public water system to conduct a monitoring program for unregulated contaminants.

5. Non-transient Non-community Water Systems

Public water systems are defined in the Act at section 1401(1)(D)(4) as those systems which provide piped water for human consumption and have at least 15 connections or regularly serve at least 25 people. The category "public water system" is composed of community and non-community water systems. The community water system is one which serves at least 15 connections used by year-round residents or regularly serves at least 25 year-round residents (40 CFR 141.2). Non-community systems, by definition, are all other water systems. Non-community systems include transient systems (e.g., campgrounds, gas stations) and non-transient systems (e.g., schools, workplaces, hospitals which have their own water supply and serve the same population over six months of a year), as explained in more detail later.

6. Public Notification

Section 1414(c) of the Act requires the owner or operator of a public water system which fails to comply with an applicable maximum contaminant level or treatment technique requirement, testing procedure, or section 1445(a) monitoring requirement to give notice to the persons served by the water system. Owners and operators of public water systems for which variances or exemptions are in effect, or which fail to comply with the requirement of any schedule imposed pursuant to a variance or exemption, must also give notice. Section 1445(a)(5) also requires public water systems to notify the persons served by the water system and the Administrator of EPA of the availability of the results of monitoring for unregulated contaminants.

B. Regulatory Background

On June 12, 1984 (49 FR 24330), EPA proposed MCLGs for the eight VOCs covered in today's notice: Benzene, carbon tetrachloride, 1,2-dichloroethane, trichloroethylene, **0000001595**

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dichloroethylene, 1,1,1-trichloroethane, para-dichlorobenzene, and vinyl chloride. On November 13, 1985, EPA published the final MCLGs and proposed MCLs for these eight VOCs (50 FR 46880 and 50 FR 46902). Detailed discussions of the history of the regulation of VOCs in drinking water together with information on occurrence in drinking water and any adverse effects of human exposure were presented in these notices. This background is summarized below. EPA proposed to amend the MCLG for para-dichlorobenzene (p-DCB) and repropoed the MCL for p-DCB on April 17, 1987 (52 FR 12876).

1. MCLGs, MCLs, and Monitoring

In the November 13, 1985, notice for substances considered to be known or probable human carcinogens, EPA set the MCLGs at zero. For substances it did not consider known or probable human carcinogens, EPA set the MCLGs based upon chronic toxicity data. Table 1 summarizes the final MCLGs for these VOCs. The Chemical Manufacturers Association, the Halogenated Solvents Industry Alliance, and the Natural Resources Defense Council each filed petitions for review of one or more of these MCLGs. These petitions are pending before the U.S. Court of Appeals for the District of Columbia Circuit.

The establishment of an MCLG at zero does not imply that actual harm would necessarily occur to humans at a level somewhat above zero, but rather that zero is an aspirational goal, which includes a margin of safety, within the context of the Safe Drinking Water Act. MCLs, even though set at levels above aspirational MCLGs, based on feasibility considerations, are also considered safe levels that are protective of public health.

EPA proposed the MCLs for the eight VOCs based upon an evaluation of (1) the availability and performance of treatment technologies [Best Technology Generally Available (BTGA), under Sections 1412 and 1415, was identified as PTA or GAC], (2) the availability, performance, and cost of analytical methods, and (3) an assessment of the costs of application of various technologies to remove VOCs from drinking water to various concentrations. Table 1 summarizes the final MCLGs and the proposed and final MCLs that EPA is promulgating in this rule.

TABLE 1. -- FINAL MCLGS AND PROPOSED AND FINAL MCLs FOR THE VOCs

Compound	Final MCLG (mg/l)	Proposed MCL (mg/l)	Final MCL (mg/l)
Benzene	Zero	0.005	0.005
Vinyl chloride	Zero	.001	.002
Carbon tetrachloride	Zero	.005	.005
1,2-Dichloroethane	Zero	.005	.005
Trichloroethylene	Zero	.005	.005
p-Dichlorobenzene *	0.075	.005	.075
1,1-Dichloroethylene	.007	.007	.007
1,1,1-Trichloroethane	.20	.20	.20

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* Reproposed on April 17, 1987, at zero and 0.005.

As described above, the Agency proposed to amend the MCLG and repropoed the MCL at 52 FR 12876 (April 17, 1987) for para-dichlorobenzene (which is the common name for 1,4-dichlorobenzene). These proposals were based upon results of a new National Toxicology (NTP) study. Based on a preliminary assessment of the total weight of evidence of the toxicological studies, EPA proposed to reclassify p-dcb as a Group B2 substance under the Agency's Guidelines for Carcinogen Risk Assessment at 51 FR 33992 (September 24, 1986).

This notice on p-dcb also indicated that EPA was considering classification of p-dcb in Group C instead of B2. The Agency asked for public comment on the appropriate classification based on the weight of evidence.

In the November 1985 notice, EPA proposed to require non-transient non-community water systems to meet the same requirements as community water systems by broadening the definition of "community water systems." This category of public water systems includes such systems as schools and factories where the same consumers may be exposed not only for part of the day but throughout much of the year, and often for many years.

At the same time that EPA proposed the MCLs, it also proposed minimum compliance monitoring requirements consisting of one initial round of monitoring to determine the extent of contamination and certain follow-up monitoring requirements if the initial round of monitoring indicated VOC contamination. The November 1985 notice also proposed monitoring requirements for 51 additional unregulated contaminants (all VOCs) under Section 1445. These requirements were very similar to the compliance monitoring requirements proposed for the eight MCLs. The major difference was that for the unregulated contaminants only one round of monitoring was proposed (the compliance monitoring requirements called for repeat sampling ranging in frequency from quarterly to every 5 years, depending on the prior monitoring results and a determination of a system's vulnerability to contamination).

2. Reporting and Public Notice

EPA also proposed reporting and public notice requirements for VOCs in the November 1985 notice. The proposed requirements were identical to those currently in place under the National Interim Primary Drinking Water Regulations (now simply "National Primary Drinking Water Regulations"). No change in the public notice requirements was proposed at that time.

For unregulated contaminants, the proposed regulations would have required the PWS to notify its consumers of the availability of the analytical results of the unregulated contaminant monitoring and to submit a representative copy of each public notice to the State. In addition, the results of the monitoring were to be submitted to the State.

In response to the SDWA amendments of 1986, which revised the public notification requirements in Section 1414(c), EPA recently proposed changes to public notification requirements in 52 FR 10972 (April 6, 1987). That proposal includes specific explanations of the potential health risks of exposure to the eight VOCs in today's final rule. Those explanations were proposed to be required in each public notice for failure to comply with any MCL.

C. Public Comments on the Proposal

EPA requested comments on all aspects of the November 13, 1985, proposal and the April 17, 1987, reproposal. A detailed summary of the comments received and the Agency's responses are presented in the document "Summary of Comments and EPA responses on the Proposed MCLs for the VOCs, Reproposed MCLG/MCL for para-Dichlorobenzene, and Requirements for Monitoring Unregulated Contaminants," available in the public docket. General summaries of comments, with responses, pertaining to specific MCL issues are presented in the relevant sections of this notice.

EPA received over 250 written comments on the November 1985 proposed rule, including 39 from individuals, 20 from companies, 45 from water utilities or water utility associations, 10 from trade associations, 101 from Federal agencies, States, and local governments, and 44 from other groups (primarily mobile home park operators). EPA held public hearings in Washington, D.C., on January 13, 1986, and received an additional 10 comments at that time. Additional comments were received at the May 4, 1987, public hearing as well as in writing during the public comment period on the April 1987 repropoed MCLG and MCL for

para-dichlorobenzene.

III. Explanation of Today's Actions

A. Non-Transient Non-Community Water Systems

In the November 1985 notice, EPA proposed to redefine the term "community water system" to include certain non-community water systems as follows:

Community Water System means a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 of the same persons over 6 months per year.

The purpose of the change was to protect nonresidential populations of more than 25 people who, because of regular long-term exposure, might incur long-term risks of adverse health effects similar to those incurred by residential populations. The change was designed to include systems serving more than 25 persons in such places as workplaces, offices, and schools, that have their own water supplies.

EPA requested comment on this proposal. About half the commenters who addressed this issue supported the change, citing the potential health risks from exposure in these non-transient situations. The other commenters stated that the resource burden to the States and the regulated community would be excessive and felt that the potential benefits would not outweigh the costs.

EPA believes applying NPDWRs to such systems is protective of public health and should be implemented. EPA believes the risks to consumers commonly associated with long-term exposures to contaminated drinking water in many cases could also apply to NTNCWS drinking water consumers, such as factory employees and school children exposed to the same drinking water source over a number of years. The chronic health risks to consumers in non-transient water systems would be similar to residential populations served by community water systems, since one can estimate that one-third to one-half or more of the normal daily water consumption would occur at the school or workplace, and the rest at home. Therefore, EPA believes it is appropriate to apply NPDWRs to both community and non-transient non-community water systems. However, water from systems serving populations for only a brief time (e.g., campgrounds, parks, gas stations) does not pose long-term health risk such as those associated with the VOCs. Therefore, EPA believes that it is not necessary to regulate water systems that only serve transient population for agents of chronic exposure but these water systems should be regulated for acute risks (e.g., nitrates).

Instead of amending the definition of community water systems, as proposed in the November 1985 notice, EPA is promulgating a definition of "non-transient, non-community water systems" and applying the NPDWRs for the eight VOCs to those systems (as well as community water systems, as currently defined in EPA's regulations). This term includes the universe of non-transient systems that EPA included in the revised definition of community water systems it proposed. This approach is preferable to the proposed approach because if EPA amended the definition of "community water system" to include non-transient non-community systems, then all of the existing NPDWRs would apply to those systems by definition. This is not EPA's intent. However, EPA does intend to apply future NPDWRs to non-transient non-community water systems as it evaluates and revises the existing regulations, as required by the 1986 amendments to the SDWA. In conclusion, EPA is amending 40 CFR 141.2 to add a new definition as follows:

A "non-transient non-community water system" means a public water system that is not a community water system and that regularly serves at least 25 of the same persons over six months per year.

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B. MCLG for Para-dichlorobenzene

In this notice, EPA has placed p-dcb in the Group C category (limited evidence of carcinogenicity in animals). (See 51 FR 33992, September 24, 1986, for a full discussion on EPA's Guidelines for Carcinogenic Risk Assessment.) On November 13, 1985, the Agency promulgated an RMCL for p-dcb as a Group D substance, based on chronic toxicity data from the studies available at that time.

After that notice was published, the Agency received the results of a long-term study on p-dcb conducted by the National Toxicology Program (NTP) (Ref. 6). The NTP study was a chronic bioassay which used F344 rats and B6C3F1 mice. Tumors were found in both species of animals at incidences which were statistically significant. Therefore on April 17, 1987 EPA repropoed the MCLG for p-dcb. The EPA proposed the MCLG considering a classification of B2 for p-dcb but acknowledged the controversy surrounding this classification and presented an alternative Group C classification. Public comments were solicited on whether p-dcb should be classified as a B2 or C substance. The conclusions of these comments received on this proposal differed even though they were using the same criteria in the guidelines; eight commenters would place p-dcb in group C, two in Group B2.

The Agency recognizes that as with most chemicals, the evaluation of the carcinogenicity potential of p-dcb in humans is a difficult and somewhat controversial activity, in light of divergent interpretations made by the scientific community. Because it is necessary for the Agency to make a judgment based on a reasonable weighing of the evidence from the data at hand, at this time p-dcb is being classified in category C (possible human carcinogen).

At issue in the controversy of the classification is whether there exists "sufficient" evidence of carcinogenicity (i.e., B2 classification) or whether there is only "limited" evidence of carcinogenicity (i.e. Group C).

A Group B2 substance is defined by the following factors:

An increased incidence of malignant tumors or combined benign and malignant tumors in:

- (a) Multiple species or strains,
- (b) In multiple experiments (e.g., with different dose levels and routes of exposure) or
- (c) To an unusual degree in a single experiment with regards to a high incidence, unusual site or type of tumor, or early age at onset.

A Group C is defined by the following factors:

Having limited animal evidence of carcinogenicity in the absence of human data in which:

- (a) The studies involve a single animal species, strain or experiment and do not meet criteria for sufficient evidence.
- (b) The experiments are restricted by inadequate dosage levels, inadequate duration of exposure, or inadequate reporting, or
- (c) The studies show an increase in the incidence of benign tumors only.

As pointed out in these Guidelines, this classification is not meant to be applied rigidly or mechanically, but a balanced judgment of the totality of the available evidence needs to be considered. This weight of the evidence approach can increase the number of reasonable interpretations to the same data base.

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Decision Process

Evaluating the increased male rat kidney tumors and liver tumors in male and female mice of the NTP 1986 bioassay, p-dcb might be tentatively classified in Group B2; probable human carcinogen. However, when reviewing the total weight of evidence at this juncture, p-dcb could also be classified in Group C; possible human carcinogen. Factors relevant to determining weight of evidence include: 1) evidence of carcinogenicity, 2) structure/activity relationships, 3) genotoxicity test findings, and 4) results of appropriate pharmacokinetic and toxicological observations.

Because the carcinogenicity bioassays (discussed under *Evidence of Carcinogenicity*) do not provide unequivocal evidence of carcinogenic potential for humans, it is necessary to consider all factors in determining the weight of evidence for p-dcb carcinogenicity.

(1) *Evidence for Carcinogenicity.* Evidence for the carcinogenicity of p-dcb is primarily limited to the NTP study of F344 rats and B6C3F1 mice. In this study, rats and mice were exposed to two doses of p-dcb in corn oil administered via gavage. The NTP concluded that there was clear evidence of carcinogenicity both for male rats as shown by an increased incidence of renal tubular cell adenocarcinomas and for mice of both sexes as shown by increased incidences of hepatocellular carcinomas and hepatocellular adenomas. No evidence of carcinogenicity was seen in female rats.

The issue in interpreting the guidelines is to determine the relevance of both the male rat kidney and mouse liver tumors to human carcinogenesis.

Induction of male rat kidney tumors by several nongenotoxic organic chemicals has been linked to the presence of hyaline droplets composed of alpha-2u-globulin, a protein which has not been detected in female rats, mice or humans. There is evidence for the formation of hyaline droplets in male rats given p-dcb orally. It has been asserted by several investigators and commenters, and supported by substantial data, that alpha-2u-globulin is essential for hyaline droplets in the male rat kidney. Presence of hyaline droplets seen only in the male rat kidney, which was the target organ in the NTP bioassay, and lack of hyaline droplets in the female rat kidney, which was not a target organ, supports the hypothesis that hyaline droplets formation may have limited significance for human exposure to p-dcb. The mechanism of carcinogenesis is not absolutely certain but the involvement of alpha-2u-globulin is a probable and sound scientific explanation that has been developed from a large body of mechanistic and pharmacokinetic studies on this chemical.

The significant increase in mortality indicated that the MTD was exceeded for the high dose male rats.

Diminished toxicological significance might be ascribed to mouse liver tumors, which are induced by a number of chlorinated hydrocarbons. As with tumors of the male rat kidney, theories have been proposed which argue that the mouse liver response is not relevant to humans. Explanations are still tentative and the possible relevance to human carcinogenicity is a current topic of debate.

Other bioassays have been performed which although having some shortcomings confirm the negative results in the low dose NTP bioassay results. Alderly Part Wistar rats were exposed to multiple doses of p-dcb via inhalation for 76 weeks, followed by an additional 36 weeks of observation (Riley et al., 1980; described in Ref. 8). No increases in tumor incidence were observed. Comparisons of this study with the NTP bioassay are made difficult because of the differences in the route and duration of exposure. However, if 0.1 liter/minute was assumed as the breathing rate for 500 gram rats exposed to p-dcb for five hours a day, five days/week for seventy-six weeks, the estimated daily oral dose would be 178 mg/kg. This estimated dose is slightly higher than the low dose of 150 mg/kg in male rats, which did not produce a significant increase in kidney tumors, as reported from the NTP study. While the

shorter duration of exposure may be responsible for diminished tumorigenic response, the variety of toxic effects (increase in liver, kidney, heart and lung weights, increase in urinary protein and coproporphyrin output) in the high dose group (500 ppm) indicate that the MTD was approached.

Subchronic studies have demonstrated evidence of liver and kidney toxicity and a variety of other toxic effects from p-dcb exposure to animals either via gavage or inhalation (Hollingsworth, 1956, 1958; described in Ref. 8). No evidence of carcinogenicity was found, but the short duration of these studies (6-month duration) precludes detecting carcinogenic effects unless the latency would be unusually short and the compound were a potent carcinogen.

No evidence of carcinogenicity in humans has been reported, which is not unusual. Therefore, inadequate data are available to assess the weight of evidence for carcinogenicity from epidemiological/case studies in humans.

Thus, considering the totality of evidence, the available bioassay data are equivocal as a basis for extrapolating to humans and the epidemiological data are inadequate. In the judgment of the Agency, a Group C classification for p-dcb would be more appropriate than a B2 classification based upon the information currently available.

(2) *Structure-Activity*. Compounds with similar chemical structures have been tested in long-term carcinogenicity bioassays, but no clear evidence of carcinogenicity has been reported. Such structure-activity information can be useful when evaluating closely related chemicals.

Two compounds with similar structures to p-dcb (orthodichlorobenzene (o-dcb) and monochlorobenzene (mcb)) have been tested in NTP bioassays. As with p-dcb, the compounds were administered in corn oil via gavage to F344 rats and B6C3F[1] mice. Under test conditions, o-dcb was not carcinogenic at doses of 60 and 120 mg/kg administered for 103 weeks. For mcb, an increase of neoplastic nodules of questionable statistical significance was found for high-dose male rats (120 mg/kg). Both o-dcb and mcb have been classified as Group D: inadequate evidence for carcinogenicity.

Metabolites of p-DCB (2,5-dichlorophenol and its hydroquinone) have not been tested for carcinogenicity. 2,4-Dichlorophenol was administered in drinking water in a two-year bioassay in rats (Exon and Koller, 1985; described in Ref. 8) and found to produce no increase in tumors, but was cocarcinogenic when administered with ethylnitroso urea (ENU). 2,4-Dichlorophenol has not been formally classified, but could be categorized as Group D: inadequate evidence for carcinogenicity.

Structure activity relationships alone cannot be the sole basis for discounting positive findings, but they do detract from the overall weight of evidence of carcinogenicity in this case.

(3) *Genotoxicity Tests*. p-Dcb was determined not to be genotoxic from a variety of short-term genotoxicity bioassays. Therefore, it is less likely that it could be carcinogenic by a genotoxic mechanism. Genotoxicity is often associated mechanistically with carcinogenicity. Some non-genotoxic substances are carcinogenic by unknown mechanisms.

p-Dcb is not mutagenic when tested in *Salmonella typhimurium* or in the *E. coli* WP2 system. Increased frequency of back mutation was observed on the methionine requiring forms in the fungus *Aspergillus nidulans*, however this finding is not considered significant.

p-Dcb was not found to induce forward mutations in mouse lymphoma cells, sister chromatid exchange in Chinese hamster ovary cells or unscheduled DNA synthesis in human lymphocytes. Negative results were also obtained in cytogenicity studies with rat bone marrow cells and a dominant lethal study in CD-1 mice following exposure to p-dcb.

(4) *Pharmacokinetic and Toxicological Observations.* Commenters also raised questions on the relevance of the results of the NTP bioassay to exposure of humans to p-DCB via drink water. Issues include the toxicological significance of the mode of administration (gavage vs. drinking water) and the vehicle used (corn oil vs. drinking water).

With respect to both mode of administration and vehicle, no data are available specifically on p-dcb, but bioassays on other chlorinated hydrocarbons have shown that the pharmacokinetics of absorption/distribution differ between compounds administered in corn oil via gavage compared to drinking water administration. The issue that the corn oil vehicle itself may affect hepatic metabolic capabilities and influence the susceptibility of the mouse to hepatic tumors has been a subject of controversy. No. data are available specifically on p-dcb.

Conclusion

Therefore, in considering the total weight of evidence: One positive study in two animal species, a partially corroborating study in one species, no human evidence, no replication of the results in animals, negative evidence of carcinogenicity in structurally similar compounds, negative mutagenicity studies, uncertainties with mode of administration and controversy surrounding the significance of the rat kidney and mouse liver tumor results, at this time the EPA establishing the MCLG and MCL for p-DCB considering p-dcb as a Group C carcinogen.

The classification of p-dcb as a Group B2 or Group C substance is a controversial one. EPA will reassess this classification as new information becomes available. This reclassification results in a reduction of the prior MCLG (RMCL) by a factor of 10 from 0.75 to 0.075 mg/l.

An MCLG of 0.075 mg/l (75 mu g/l) has been calculated based on chronic toxicity data. The MCLG was calculated as follows:

$$\text{DWEL} = \text{reference dose} \times \text{body weight} / \text{daily water consumption} = (0.1 \text{ mg/kg/day})(70\text{g}) / 21/\text{day} = 3.75 \text{ mg/l}$$

MCLG = drinking water equivalent level X relative source contribution / additional uncertainty factor

$$\text{MCLG} = 3.75 \times 0.2 / 10 = 0.075 \text{ mg/l (75 mu g/l)}$$

Where the reference dose is calculated as:

$$\text{RfD} = \text{no observable effect level} / \text{uncertainty factor} = 150 \text{ mg/kg/day (5)} / 1000 (7) = 0.1 \text{ mg/kg/day}$$

The classification of Group C is also consistent with the recommendations of the National Drinking Water Advisory Council, the transcript of a meeting held by the Halogenated Solvents Subcommittee of the EPA Science Advisory Board on p-dcb. Eight out of the ten commenters who responded to the request for comment of the para-dichlorobenze classification supported the Class C decision.

Had p-dcb been assigned to Group B2, the 95% upper-limit carcinogenic potency factor for humans, $q[1]^*$, would be the basis for the quantitation. A "what if" calculation for p-dcb, using the draft $q[1]^*$ value is 2×10^{-2} (mg/kg/day) $^{-1}$ by the multistage model and male mouse liver tumor data indicated an upper-limit individual lifetime cancer risk of 4×10^{-5} for a 70 kg human drinking 2 L/water a day for a lifetime (assumed to be 70 years) exposure to drinking water containing 75 mu g/L.

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C. MCLs for VOCs

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In this rule, EPA is promulgating MCLs for the eight VOCs as follows:

Compound	Final MCL (mg/1)
Benzene	0.005
Vinyl chloride	0.002
Carbon tetrachloride	0.005
1,2-Dichloroethane	0.005
Trichloroethylene	0.005
para-Dichlorobenzene	0.075
1,1-Dichloroethylene	0.007
1,1,1-Trichloroethane	0.2

As noted earlier, section 1412(b)(4) of the Act requires EPA to set MCLs as close to the MCLGs as is feasible. Section 1412(b)(5) of the Act defines "feasible" to mean "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)," i.e., "BAT."

This provision represents a change from the provision prior to 1986, which required EPA to judge feasibility on the basis of "best technologies generally available" ("BTGA"). The 1986 amendments changed BTGA to BAT and added section 1412(b)(5), which specifies that the technology selected as BAT must be tested for efficacy under field conditions, not just under laboratory conditions. The legislative history explains that Congress removed the term "generally" to assure that MCLs "reflect the full extent of current technology capability." [S. Rep. No. 56, 99th Cong., 1st Sess., at 6 (1985)]. Read together with the legislative history, EPA has concluded that the statutory term "best available technology" is a broader standard than "best technology generally available" and that this standard allows EPA to select a technology that is not necessarily in widespread use, as long as it has been field tested beyond the laboratory. In addition, EPA believes this change in the statutory requirement means that the technology selected need not necessarily have been field tested for each specific contaminant. Rather, EPA may project operating conditions for a specific contaminant using a field tested technology from laboratory or pilot systems data.

Based on the statutory directive for setting MCLs, EPA derives the MCLs from an assessment of a range of pertinent factors, including the availability and performance of BAT, the costs of these technologies for different size water systems, and the number of water systems that would have to install technologies. EPA also evaluates the availability of analytical methods and the reliability of analytical results as well as the resulting health risks of various contaminant concentration reduction levels attainable by BAT. For drinking water contaminants, the target reference risk range for carcinogens is 10<-4> to 10<-6> and most regulatory actions in a variety of EPA programs have generally fallen in this range using conservative models which are not likely to underestimate the risk. Of course, MCLs could be set outside the range depending upon the feasibility of achieving a specific level.

1. Treatment Technologies

As explained in the November 1985 proposal, EPA examined a number of treatment processes for their potential to reduce the level of VOCs in drinking water. These technologies are discussed in the document "Technologies and Costs For The Removal of Volatile Organic Chemicals From Potable Water Supplies." (Reg. 2). (A draft of this document was available at the time of the proposal. The final document is available from the National Technical Information Service at the address listed in Section VI of this notice.)

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In reviewing the different technologies available, EPA looked at the following factors : Removal efficiency, degree of compatibility with the other water treatment processes, service life, and the ability to achieve compliance for all the water in a public water system.

Based on these criteria, in the November 1985 notice, EPA proposed granular activated carbon (GAC) and packed tower aeration (PTA) as "best" technologies for removing VOCs from drinking water. As described in that notice (50 FR 46914), these technologies have the following characteristics: good removal efficiencies (90 to 99 percent); compatibility with other types of water treatment processes; reasonable service life; and ability to achieve compliance for all the water in a public water system. In addition, these two technologies are commercially available and have been used successfully to remove VOCs in ground water from both influents and effluents in many locations across the United States.

In the 1986 amendments to the Safe Drinking Water Act, Congress specified in section 1412(b)(5) of the Act that:

granular activated carbon is feasible for the control of synthetic organic chemicals, and any technology, treatment technique, or other means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon.

For all the VOCs except vinyl chloride, EPA has identified GAC as technology that is effective for removing VOCs. PTA is equally effective. Therefore, these two technologies are "best" for these seven VOCs. PTA is more effective than GAC for vinyl chloride, as noted below.

Vinyl chloride differs from the other VOCs because it is a gas under typical temperature and pressure conditions. Therefore, vinyl chloride is most easily removed by PTA treatment. Because vinyl chloride is a gas and a known human carcinogen, no laboratory isotherms have been developed by EPA or reported in the literature. However, one investigator reported sporadic removal of vinyl chloride from ground water in Florida using GAC (Symons, 1978). This investigator also noted that vinyl chloride was the only one of a number of related, low molecular weight VOCs to show such an erratic pattern. A more recent, unpublished study of ground water in Wisconsin (EPA, 1987) showed less erratic removals at a higher empty bed contact time and lower raw water concentrations. It is difficult to interpret either of these studies. Therefore, because PTA has been demonstrated to be extremely effective and GAC may, under some circumstances, exhibit poor or erratic removal, EPA is not specifying GAC as "best" for the removal of vinyl chloride. PTA, however, is "best" for removal of this contaminant.

Also, it should be noted that the data used to determine removal efficiencies were based on performance for ground water. EPA expects that GAC, applied to surface water, would achieve lower performance efficiencies because of the higher levels of organic carbon found in surface water which cause more rapid depletion of the capacity of the GAC (ground waters typically have very low levels of background organic carbon) (See Reference 2).

In addition to GAC or PTA, there are other technologies which may remove VOCs from drinking water, e.g., resins, powdered activated carbon. However, EPA has concluded that these technologies are inferior to GAC and PTA for various reasons, e.g., the technology is not commercially available or the removals are lower and/or less consistent. For a further discussion of other technologies EPA considered, and why they are not designated as "best," see EPA's technology and cost document (Reference 2).

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2. Costs

As noted above, EPA is to set the MCL as close to the MCLG as "feasible," which is defined as "feasible with the use of the best technology . . . which the Administrator finds . . . is available (taking costs into consideration)." Section 1412(b)(5). In considering costs to

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determine whether the "best" technology is "available," (i.e., BAT), the legislative history of both the Safe Drinking Water Act of 1974 and the 1986 amendments indicates that EPA is to consider whether the technology is reasonably affordable by regional and large metropolitan public water systems [see H.R. Rep. No. 93-1185, p. 18 (1974) and statement of Senator Durenberger, Vol. No. 132 *Cong. Rec.* S6287 (daily ed., May 21, 1986)].

To determine BAT, EPA evaluated the costs associated with the technologies it considered "best," i.e., GAC and PTA. EPA estimates the total costs of removing each of the eight VOCs (in 1983 dollars) for both GAC and PTA based on 90-99 percent removal (i.e., from 0.5 mg/l to 0.005 mg/l). EPA looked at these costs for large systems (i.e., systems serving 100,000 to 500,000 people), medium systems (i.e., systems serving 3,300 to 10,000 people), and small systems (i.e., systems serving 100 to 500 people):

Costs for large to medium systems range from 10 to 85 cents/1,000 gallons for GAC and five to 30 cents/1,000 gallons for PTA. Costs are higher for small systems; for instance, benzene removal using GAC would cost approximately \$1.50/1,000 gallons, and removal using PTA would cost 86 cents/gallon. For concentrations of VOCs expected in ground waters, GAC can achieve a level of 0.005 /mg/l at reasonable empty bed contact times and carbon usage rates. This is reflected in the costs displayed in Table 5. The costs are based on carbon usage rates that estimate breakthrough at three to six months; however, in a number of locations GAC has achieved VOC levels below detection for 12 months or longer. The empty bed contact time is reflected in the capital costs and carbon usage rates in the annual O&M costs. EPA believes that the costs incurred by even the smallest system size (25-100 people) are reasonable and affordable. (Reference 2).

While most commenters agreed with the cost estimates presented in the proposal, several claimed that the Agency's treatment cost estimates were too low. EPA believes that the range of treatment cost estimates are representative. The differences between EPA's estimates and those presented by the commenters are due to the unique site-specific factors considered by the commenters (e.g., variations in costs of land, zoning requirements for tower height, housing for columns, and labor and material costs).

Some commenters stated that the Agency should consider the cost of air pollution control for VOC emissions from packed tower aeration. EPA does not believe that it is appropriate to factor the cost of air pollution control into the treatment costs since assessments show air emissions to be negligible from aeration treatment of drinking water to remove VOCs (See Ref. 5, Peters and Clark, 1985). For further information on air emissions of VOCs, see the November 1985 notice (50 FR 46911, November 13, 1985).

For contaminants with MCLGs set at a non-zero level (substances in carcinogenicity Group C, D, or E), i.e., 1,1-dichloroethylene, 1,1,1-trichloroethane, and para-dichlorobenzene, EPA has concluded that the removal costs cited above are affordable. Therefore, because these technologies meet the treatment criteria and the costs are reasonable, GAC or PTA are BAT for these three contaminants. Since these technologies can easily remove these contaminants to levels below their MCLGs, it is feasible to set MCLs equal to the MCLGs. EPA has set the MCLs accordingly.

For contaminants with MCLGs at zero (substances in either Group A or B), the analysis is somewhat different because detection and achievement of zero concentration in principle cannot be achieved. In the MCL-setting process, therefore, EPA evaluates the feasibility of achieving levels as close to zero as feasible. Based on the costs and the availability/performance of treatment described above, EPA has concluded that GAC and PTA are BAT (except that GAC is not BAT for vinyl chloride, since it is not the "best" technology).

To determine what level was feasible as BAT, EPA examined the total compliance costs at various levels of contamination (as well as the individual compliance costs summarized above). For all the contaminants with MCLGs at zero, except for vinyl chloride, if the MCLs

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were set at 0.005 mg/l, EPA estimates that 1300 CWS would need to install treatment at a total capital cost of \$280 million to achieve compliance. If EPA set the MCLs at 0.001 mg/l for these contaminants, EPA estimates that many more systems, i.e., a total of 3800, would have to install treatment at a total capital cost of \$1,300 million to achieve compliance. EPA believes that, considering the efficacy and the nationwide costs associated with these different levels, as specified in the Act, the costs associated with the additional removals, i.e., from 0.005 mg/l to 0.001 mg/l, are not warranted. Therefore, the Agency has established MCLs for trichloroethylene, carbon tetrachloride, 1,2-dichloroethane, and benzene at 0.005 mg/l.

For vinyl chloride, EPA has set the MCL at 0.002 mg/l. This lower level reflects the treatment capability of PTA that would be used to remove vinyl chloride, and it is not expected to result in any increased cost over an MCL of 0.005 mg/l. EPA believes that very few, if any, public water systems will need to install treatment solely to control vinyl chloride. Because systems with vinyl chloride present at any level virtually always have one or more of the other VOCs covered by this rule present at levels higher than the promulgated MCL for these VOCs, these systems will be treating their water to comply with the MCLs applicable to those other VOCs and the same treatment (PTA) will also remove the vinyl chloride to 0.002 mg/l.

EPA estimates the total compliance costs to meet the eight MCLs at \$300 million (total present value costs) and \$22.5 million (total annual costs) (See Ref. 3, "Economic Impact Analysis of Proposed Regulations"). EPA estimates the annual cost per family to be \$41 per year for a small system, \$12 per year for a medium system, and \$3 per year for a large system.

3. Other Factors

The other factors EPA examined support its MCL determinations. They are explained below.

Analytical Methods. The Agency also examined the analytical methods available for the measurement of volatile organic chemicals in drinking water and summarized its findings in the November 1985 notice. Based on this review, the Agency has determined that analytical methods currently exist which can reliably measure VOCs in drinking water. In addition, EPA has concluded that the cost of sample analysis at intervals necessary to assure detection of MCL violation is economically feasible for all public water systems. Costs are estimated to be approximately \$150 to \$200 per sample analysis. Further discussion of available analytical methods is included in the section on compliance monitoring. The MDL is the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the true value is greater than zero. These MDLs are the result of measurements made by a few of the most experienced laboratories under non-routine and controlled ideal research-type conditions.

MDLs and PQLs. The MDL is used by individual laboratories to determine the laboratory-specific minimum detection capabilities. EPA has gathered information indicating that laboratories in general are able to achieve MDLs of 0.0005 mg/l or lower with the available VOC methods (Ref. 1). Specifically, under single-laboratory, ideal conditions, the method detection limits (MDLs) of the eight VOCs have been determined to range from 0.0002 to 0.0005 mg/l.

In the November 1985 proposal, EPA defined the "practical quantitation level" (PQL) as the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. PQLs thus represent a level considered to be achievable on a routine basis. The basis for setting PQLs is (1) quantitation, (2) precision and accuracy, (3) normal operations of a laboratory, and (4) the fundamental need (in the compliance monitoring program) to have a sufficient number of laboratories available to conduct the analyses.

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The PQL is analogous to the limit of quantitation (LOQ) as defined by the American Chemical Society. Both the LOQ and the PQL define the concentration of an analyte above which is the region of quantitation and below which is the region of less certain quantitation. The difference is that where the PQL is an inter-laboratory concept while the LOQ is specific to an individual laboratory. The Agency developed the PQL concept to define a measurement concentration that is time and laboratory independent for regulatory purposes. The LOQ and MDLs, although useful to individual laboratories, do not provide a uniform measurement concentration that could be used to set standards.

PQLs for the VOCs were determined based on the MDL and surrogate test data. In the past, EPA has estimated the PQL at five to ten times the MDL and, in the November 1985 notice, EPA suggested setting PQLs at this general range. In the notice EPA used the results of inter-laboratory studies to confirm this estimate. The PQLs based on these laboratory data are considered a "two-step removed" surrogate for actual laboratory performance, first because they are estimated from another measurement (the MDL) and second, because they are derived from laboratory performance under ideal circumstances. Therefore, they do not actually represent the results of normal laboratory procedures, but are a model of what normal procedures might achieve. Specifically:

- (1) Laboratories receive performance evaluation samples in which a limited number of concentrations are analyzed and the samples do not have matrix interferences as might actual samples;
- (2) PQLs are based on EPA and State laboratory data which are considered to be representative of the best laboratories, but not all laboratories; and
- (3) Samples are analyzed under controlled ideal testing conditions which may not be representative of routine practice.

For these reasons, the PQL represents a relatively stringent target for routine performance. EPA expects that the PQLs in this rule will push laboratories to perform at a higher level than they would otherwise. In the range between the MDL and the PQL, quantitation of contaminants can still be achieved, but not necessarily with the same precision and accuracy possible at the PQL. As measurements approach the MDL, there is much less confidence in quantitation. Thus, PQLs set a target performance level for laboratories using a specified set of precision and accuracy limitations. In this manner, PQLs provide consistency in implementing a regulatory program, in a practical way, where both quality control and quality assurance is critical.

Most commenters agreed with the PQL concept; however, several stated that the PQLs should be verified further through additional multi-laboratory studies. For instance, several commenters were critical of the PQL for vinyl chloride, stating that the level should be based on multi-laboratory data as opposed to simply being set at a value of five times the MDL. EPA agrees that the PQLs should be further verified; as explained in Reference 1, the Agency collected additional multi-laboratory data including data on vinyl chloride, and used these data to set the final PQLs.

One commenter felt that PQLs should be replaced with the LOQ concept as described above. EPA does not agree that the PQL should be set based upon the LOQ because the LOQ is dependent on the precision attainable by a specific laboratory, which can vary from day to day as well as among laboratories. Thus, the LOQ is not designed to assess the performance of a large number of good laboratories; instead, it is laboratory-specific and therefore is not suitable for setting criteria for national standards.

Some commenters stated that the PQLs were set at too high a level and suggested 0.001 mg/l, while others believed that the PQLs were too low. A PQL range from 0.02 to 0.04 mg/l for benzene was suggested by one commenter.

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EPA disagrees with the comments that the PQLs were set at the wrong level; the levels were selected based on multi-laboratory data which confirmed the general rule of five to ten times the MDL. Setting the PQLs at higher or lower levels would not be consistent with the data. EPA recognizes that many laboratories have reported data at levels less than the PQL; however, the Agency does not consider the data sufficient upon which to base national standards considering the other data available. Again, PQLs provide for consistency in data quality from a diverse group of laboratories across the country, and provide routine performance goals that many laboratories must strive to achieve.

As explained in Reference 1, the PQLs are 0.005 mg/l for all the VOCs except vinyl chloride. EPA generally based the PQLs upon a laboratory performance criterion of +/-20 percent or 40 percent, depending on the concentration, for each individual VOC except for vinyl chloride which was +/-40 percent. This provides a relatively stringent performance target for laboratories but one that has been demonstrated to be achievable by three-quarters of the "best" (EPA and State) laboratories under evaluation conditions. It is expected that the remaining laboratories will need to upgrade their performance in order to meet this criterion. For vinyl chloride, the PQL is 0.002 mg/l (rounded from 0.0015 mg/l for the reasons discussed in Reference 1). The PQL of 0.002 mg/l recognizes that on the one hand the precision/accuracy associated with measuring vinyl chloride is expected to be less than for the other VOCs; but that, on the other hand, vinyl chloride is a known human carcinogen of high potency and the risk posed by each unit of exposure could be higher than for the other VOCs. Because of this latter factor, EPA believes it is appropriate to accept slightly less precise data in order to seek to obtain more stringent levels of control. Technical assistance to laboratories that wish to be certified to analyze vinyl chloride is available for EPA-EMSL in Cincinnati.

For each VOC, the PQL is equal to or less than the MCL. Therefore, laboratories will be able to reliably determine whether systems are in compliance with the MCLs.

Health Risks. EPA examined the theoretical maximum health risks expected at various contaminant levels. These health risks include non-cancer risks, as well as cancer risks. The upper-limit unit risk estimates from the animal data are derived from a linearized multistaged nonthreshold extrapolation model that is currently programmed as GLOBAL 83. Justification for its use is presented in EPA's Guidelines for Carcinogenic RISK Assessment. While recognizing that alternative statistical modeling approaches exist (e.g., one-hit, Weibull, log-probit and logit models, and maximum likelihood estimates), the range of risks described by using any of these modeling approaches has little biological significance unless data can be used to support the selection of one model over another. In the interest of consistency of approach and of providing an upper bound estimate for the potential cancer risk, the Agency recommends the use of the linearized multistage model. EPA considers this model and resulting risk estimates to be an upper-limit value in the sense that the true risk is unlikely to be higher and may be lower. An established procedure does not yet exist for making "most likely" or "test" estimates of risk within the range of uncertainty derived by the upper and lower limit values.

Table 2 presents sample risk estimates calculated at the 95 percent confidence limit using the multi-stage model for the five VOCs which are considered known or probable human carcinogens. EPA's Carcinogen Assessment Group (CAG) calculated these numbers based on the assumption of two liters of water ingested daily over a lifetime of 70 years for a person weighing 70 kilograms (kg). The Agency calculates these risk estimates so that they are not likely to underestimate the actual risks, and are conservatively used to evaluate "worse case" scenarios for the purpose of regulatory impact analysis.

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TABLE 2 -- AN EXAMPLE OF UPPER BOUND LIFE-TIME CANCER RISK (10^{-5}) ESTIMATES FOR VOCs CATEGORIZED AS KNOWN OR PROBABLE HUMAN CARCINOGENS

Compound	Concentration in drinking water (mg/l)	
	Estimate	Rounded *
Trichloroethylene	0.026	0.03
Carbon tetrachloride	.0027	.003
1,2-Dichloroethane	.0038	.004
Vinyl chloride **	.00015	.0002
Benzene	.012	.01

* Risk levels are best represented by one significant figure because of the imprecise nature of the risk model extrapolations.

** Calculation using preneoplastic nodules. If preneoplastic nodules were not factored into the risk assessment, the estimated risk at 10^{-5} is 0.02 mg/l.

As mentioned above, for contaminants in drinking water, the target reference risk range for carcinogens is 10^{-4} to 10^{-6} and the MCLs EPA is promulgating in this notice generally fall in this range. EPA considers these to be safe levels and protective of public health. This is supported by the concept expressed by the WHO 1984 Guidelines for Drinking Water Quality, where it selected a 10^{-5} guideline value, and then explained that the application could vary by a factor of ten (i.e., 10^{-4} to 10^{-6}).

4. Summary of MCL Determinations

EPA considers the MCLs determined by this process to be safe and protective of the public health. Even though the MCLGs and MCLs for certain substances such as 1,1,1-trichloroethane and para-dichlorobenzene are relatively higher than those for the other VOCs, EPA does not mean to imply that systems should allow a drinking water supply to be contaminated up to those levels. Public water supplies should always strive to distribute drinking water of the highest quality feasible. In some cases, other factors such as taste and odor can be used to limit unnecessary contamination and to assure the overall safety of the water. Although they are not federally enforceable, EPA intends to publish National Secondary Regulations for these and other substances in the future based upon aesthetic considerations. The threshold for p-DCB appears to be in the range of 0.01 mg/l. The taste and odor threshold of 1,1,1-trichloroethane is about 1 mg/l.

D. Other Treatment Technologies

As stated in Section 1412(b)(6) of the Act, this regulation does not require the use of BAT (i.e., GAC or PTA), or any other technology to meet the MCLs; public water systems may use any appropriate technology acceptable to the State that treats all of the water and that results in compliance with the MCL. For example, there are many aeration technologies other than PTA (e.g., multiple tray aeration, diffused aeration, spray aeration) that remove VOCs and which a public water system may wish to install instead of BAT.

In the November 1985 notice, EPA proposed that point-of-use (POU) and point-of-entry (POE) technologies not be considered BTGA but be considered acceptable technology to meet MCLs, provided certain conditions were met (50 FR 46916, November 13, 1985). EPA did not

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propose POU or POE technologies as BAT because of difficulties associated with monitoring compliance and assuring effective treatment performance in a manner comparable to central treatment; furthermore, POU devices only treat the drinking water at a single tap. In addition to potential exposure via ingestion at untreated taps, POU devices do not treat the exposure introduced through indoor air transport (e.g., from showers or dermal contact). In addition, these devices are generally not affordable by large metropolitan water systems, which is one of the criteria for setting BAT.

In the November 1985 notice, the Agency discussed its proposal to not allow PWSs to use bottled water for compliance or to meet conditions of variances and exemptions. Public comments pointed out that bottled water may, in a few cases, be the only available "treatment technique" for the smallest systems. The Agency restated in its April 1987 notice that bottled water was not an acceptable means of meeting the MCL requirements on a permanent basis since it does not provide the same level of protection as central treatment (i.e., persons may choose not to drink bottled water) and bottled water might allow significant exposure to water which does not meet the drinking water standard during showering and other applications. However, in that notice, EPA proposed that bottled water be allowed as an interim measure to prevent an unreasonable risk to health during the time between detection of an MCL violation and achievement of compliance; it is emphasized that provision of bottled water during this interim period does not bring the PWS into compliance with the MCL; bottled water does, however, provide an acceptable source of water to drink during the interim period. In a future notice, EPA will further assess the advisability of allowing some NTNCWS and very small systems to use bottled water to meet the MCL requirements.

The majority of commenters agreed that POU/POE devices and bottled water should not be considered BAT, and that the NPDWR should not allow their use for compliance with MCLs, due to difficulties in controlling installation, maintenance, operation, repair, and potential human exposure via untreated taps. However, other commenters stated that POU/POE devices and bottled water should be considered BAT or allowed for compliance, as these technologies were often more cost-effective for some small systems than central treatment.

In this final rule, POE and POU devices are not designated as BAT because: (1) It is significantly more difficult to monitor the reliability of treatment performance and to control the operation of POE and POU devices in a manner comparable to central treatment; (2) these devices are generally not affordable by large metropolitan water systems; and (3) in the case of POU devices, not all water is treated. In addition, under this rule, POU and bottled water are not considered acceptable means of compliance with MCLs. These devices do not treat all the water in the home and could result in health risks due to exposure to untreated water. Consequently, POU devices and bottled water are only considered acceptable for use as interim measures, e.g.; as a condition of obtaining a variance or exemption, to avoid unreasonable risks to health before full compliance can be achieved. Under this rule, however, POE devices are acceptable means of compliance, because POE provides drinking water that meets the standards throughout the home. These devices may be cost-effective for small systems or nontransient non-community water systems (for which these devices would often be essentially the same as central treatment), although operational problems may be greater than for central treatment in a community system.

The SDWA requires EPA to establish necessary conditions for use of treatment that will assure protection of public health. Specifically, section 1401(l) 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." Accordingly, this rule imposes the following conditions on those systems that use POE for compliance:

- (1) *Central Control.* The public water system will be responsible for operating and

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maintaining all parts of the treatment system (i.e., the treatment device). Central ownership is not necessary, as long as the public water system maintains control of the operation of the device. Central control is appropriate and necessary to ensure that the treatment device is kept in working order.

(2) *Effective Monitoring.* As monitoring the quality of a PWS' drinking water is a central part of ensuring compliance with any NPDWR, the public water system must develop a plan and obtain State approval for a monitoring plan before it installs the POE devices. Because POE devices present a fundamentally different situation than central treatment, a unique monitoring plan must be developed. This monitoring plan must ensure that the POE devices provide health protection equivalent to central water treatment. Equivalent means that the water would meet all Primary and Secondary Drinking Water Standards and would be of acceptable quality similar to water distributed by a well operated central treatment plant. In addition to the VOCs, monitoring must include physical measurements and observations, such as total flow treated and the mechanical condition of the treatment equipment.

(3) *Application of Effective Technology.* There are no generally accepted standards for the design and construction of POE devices, and there are a variety of POE designs available. Therefore, the State must require adequate certification of performance, field testing, and, if not included in the certification process, a rigorous engineering design review of each type of device. Certification can be done by the State or by a third party acceptable to the State.

(4) *Maintenance of the Microbiological Safety of the Water.* The design and application of POE devices must consider the tendency for increases in bacterial concentrations in water treated with activated carbon and some other technologies. 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. EPA considers this condition necessary because disinfection typically is not provided after point-of-entry treatment as is normal is used in a central treatment plant.

(5) *Protection of All Consumers.* Every building connected to a public water system must have a POE device installed, maintained, and adequately monitored. If the building is sold, the rights and responsibilities of the utility customer must be transferred to the new owner with the title.

E. Analytical Methods and Compliance Monitoring Requirements

1. Analytical Methods

In the November 1985 notice, the Agency proposed the use of three analytical methods that it considered economically and technologically feasible for monitoring compliance with the VOC MCLs. These methods were:

(1) EPA Method 502.1, "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography."

(2) EPA Method 503.1, "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography."

(3) EPA Method 524.1, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry."

Capillary Column Techniques. Some commenters recommended the use of capillary column techniques for VOC analyses. The Agency evaluated capillary column methodology and agreed that they are available. Some commenters also recommended the use of detectors in series to analyze purgeable halocarbons and aromatics simultaneously. The Agency agrees and has developed Method 502.2, which provides for the use of detectors in series, and

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proposed capillary column analytical methods at 52 FR 12879 (April 17, 1987). This final rule includes the capillary column methods as approved analytical methods:

(1) Method 524.2, "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry."

(2) Method 502.2, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography with Photoionization and Electrolytic Conductors in Series."

Disapproval of the 600 Series Methods. In addition, on May 27, 1986 (52 FR 19076), EPA requested comment on whether to approve the 600 series methods (i.e., EPA's analytical methods for detecting volatile synthetic organic compounds in wastewater, Methods 601, 602, and 624 in 40 CFR Part 136) for compliance monitoring since a number of comments to the November 1985 notice suggested they be approved as well.

EPA has evaluated the comments and determined that the 600 series methods are technically very similar to the 500 series methods (e.g., the analytes covered, and the analytical columns, detectors, and chromatographic conditions are the same). However, EPA has determined that the methods are not interchangeable for various reasons. First, their analytical objectives are different. The 500 series methods emphasize detectability at low levels while the 600 series methods do not focus on measurements near the MCLs (the sample volume is 5 ml in Method 624 versus 25 ml in Method 524.1). Second, the specific quality control requirements that must be met for the 500 series and the 600 series methods are different. The performance criteria specified in the 500 series methods are more stringent than those in the 600 series methods. For example, the 500 series methods include a requirement that laboratories analyze quality control standards within 60 and 140 percent of the expected value, while the established performance criteria of the 600 series methods, while they are different for each analyte, are wider. Therefore, EPA has not included the 600 series methods in this regulation as acceptable analytical methods for compliance monitoring because these methods are not designed to maximize detectability at low levels and do not have as stringent performance criteria, as do the 500 series methods.

2. Compliance Monitoring Requirements

This final rule requires compliance monitoring to determine whether public water systems are distributing drinking water that meets the MCLs. The Agency has determined that the VOCs are Tier II contaminants in the three-tiered scheme presented in the Phase II Advance Notice of Proposed Rulemaking, published on October 5, 1983 (48 FR 45502), and further discussed in the November 13, 1985, VOCs MCL proposal (50 FR 46902). Tier II contaminants are those which are of sufficient concern to warrant national regulation (i.e., MCLs or treatment technique requirements) but which occur with limited frequency, therefore justifying flexible national minimum monitoring requirements to be applied by the State.

EPA presented three options in the November 1985 notice for VOC compliance monitoring requirements (50 FR 46919). EPA proposed option 2 for the reasons stated in that proposal. This option consisted of phasing in the monitoring requirements over a four-year period based on the size of the population served by the public water supply system. Specifically:

(1) Ground-water systems would be required to take one sample per entry point to the distribution system. Surface water systems would sample at points representative of each source in the distribution system.

(2) The initial sampling to determine compliance would consist of one sample every 3 months per source for a year for both surface and ground-water systems; the State would have the discretion to reduce the number of initial samples for ground-water systems if no VOCs were detected in that initial sample. Follow-up actions when VOCs are detected such as confirmation samples, would be left to the discretion of the State. Monitoring would be

phased in over four years with large systems first.

(3) All systems would have to conduct repeat monitoring. The repeat monitoring frequency would be based on the initial monitoring results (i.e., whether VOCs were found) and on the vulnerability of the system to VOC contamination. EPA proposed a minimum repeat monitoring frequency of once every five years for systems not considered vulnerable based on the procedure established in the initial sample (i.e., each system samples once every 3 months for a year. If no VOCs are found and the system is not vulnerable to contamination, the State may reduce the sample to that taken in the first quarter. EPA also proposed that the State be required to confirm the vulnerability status of systems once a year).

(4) Monitoring for vinyl chloride would only be required by ground-water systems detecting one or more chlorinated two-carbon VOCs (e.g., trichloroethylene, 1,2-dichloroethane, 1,1,1-trichloroethane, and 1,1-dichloroethylene) for the reasons detailed in the proposal (50 FR 46919).

(5) "Grandfathering" of previously collected data, of acceptable analytical quality (i.e., comparable to those laboratories that have interim certification), including sample analysis during Federal or State surveys, would be allowed for compliance monitoring purposes.

Appendix A to the November 1985 notice contained guidance for determining the vulnerability of public water systems to contamination by VOCs. The general criteria suggested were: (1) Population; (2) nearby use, storage, or disposal of VOCs; (e.g., proximity to landfills and RCRA sites); and (3) water source protection.

EPA encouraged the States and the PWSs to analyze their watersheds every three years by conducting a sanitary survey. EPA also encouraged systems to perform a comprehensive analysis to determine the presence of the eight VOCs proposed in the notice, the unregulated contaminants listed in this notice (in Section III.J), and as many as possible of the seventy-five other contaminants for which NPDWRs are to be promulgated by June 1989 as required by the SDWA. The State could use the results of this analysis, in part, to determine requirements for monitoring frequency for the eight VOCs.

EPA received a large number of comments on the proposed monitoring requirements. Most commenters supported the phase-in approach, as proposed. Other commenters stated that the costs of monitoring were too high and that the State should have even more discretion to determine which systems should monitor and how often. Some commenters recommended that consecutive water companies not be required to sample, that a monitoring exemption be allowed for small systems, and that EPA reduce the required sampling for systems with wells that only operate a few months a year. Other commenters recommended that the vulnerability assessment be included as part of the sanitary survey which is conducted every three years under the current NPDWR for coliforms, rather than annually. Commenters supported the provisions for "grandfathering" previous data in lieu of new data for the initial round of monitoring.

In this final regulation, EPA has retained the majority of the monitoring requirements described in the preferred option (Option 2). In the final regulation, EPA is requiring that all community water systems and NTNCWs conduct an initial round of monitoring to determine the extent of contamination of water supplies. All size systems must monitor as the occurrence data collected by EPA indicate that systems of all sizes have detected VOCs at relatively high concentrations, sometimes without apparent sources of contamination. In general, the likelihood of contamination increases with population, since areas of large commercial or industrial activity are often located in large population centers. The Ground Water Supply Survey of 1982 (Ref. 7) found that 16 percent of the smaller systems (<10,000 people) and 28 percent of the larger systems ($\geq 10,000$ people) had detectable VOCs. EPA believes that phasing in the monitoring requirements by system size is reasonable because of the greater vulnerability of the large systems and because these systems can more easily

handle the monitoring costs associated with this regulation. In addition, phasing in the requirements over a four-year period will allow the analytical laboratories to develop the capability to handle the additional samples. This is consistent with previous regulatory actions implementing the Safe Drinking Water Act (eg., trihalomethanes).

EPA has modified the sampling locations for surface water systems such that samples can be taken after treatment from entry points to the distribution system taps that are representative of each source.

EPA investigated the feasibility of compositing samples for VOC analyses in an effort to reduce the monitoring costs. Sample-compositing could then be used as a screening test to determine whether samples from multiple sampling sites may be contaminated by VOCs. EPA investigated composites of 5 different samples since a concentration in the original sample above the PQL (and the MCL for some VOCs) should still be detectable but not quantifiable in a composite sample resulting from such dilution, for example, if one of the five samples were contaminated at 0.005 mg/l and the other four were zero. Reanalysis of each sample would be required if VOCs were detected in the composite sample. The experiments conducted by EPA were done to determine whether sample-compositing would work for the VOCs (i.e., whether VOC losses could be kept to a minimum), and to determine the technique most appropriate to minimize VOC losses.

The experiments conducted involved the preparation of composite samples for GC and GC/MS analyses. The procedures investigated for each type of analysis were different because of the difference in sample size (5-ml sample purged for GC analyses; 25-ml sample for GC-MS analyses). The compositing technique that worked best for GC analyses involved the addition of five 5-ml samples to a 25-ml glass syringe and, after mixing, drawing out a 5-ml aliquot for analysis. The mixing should be done with the sample cooled at 4 deg. C to minimize VOC losses. Data collected for five replicate samples demonstrated excellent recovery for all compounds (95-100 percent) with good precision, generally 3-5 percent relative standard deviation. The recommended compositing technique for GC/MS analyses involves the injection of 5 ml of each sample directly into the purge device. For most components, recoveries were greater than 85 percent with good precision, generally between 3-5 percent relative standard deviation (Reference 1).

Based on this information, procedures for compositing samples are included in the regulations. Several points are briefly addressed below. Samples are to be collected from each source and shipped to the laboratory where they will be composited. Compositing is not done in the field. Public water systems and States that collect samples must be aware that there are some potential problems that should be kept in mind when they composite samples. It is desirable that sampling schedules be arranged in a manner that provides for collection of all samples to be composited the same day. Sample preparation and analysis must take place within the maximum holding time of 14 days. The samples collected are shipped to the laboratory where the analyst will prepare a composite sample from a series of discrete samples. This additional sample preparation step provides more opportunity for the introduction of recordkeeping errors so additional care must be taken. EPA recommends that all samples be collected in duplicate to provide an additional sample in case VOCs are detected in the composite sample. This would avoid the need to resample at each sample site to determine which site(s) may be contaminated. If VOCs are detected in the composite sample, the original samples cannot be reanalyzed because of head space problems created when the first aliquot was taken. Reanalysis must be conducted for each of the duplicate samples, provided the maximum storage time of 14 days has not been exceeded. Resampling must be done immediately where one or more VOCs are detected if no duplicates are available.

The greatest limitation of compositing samples from different sources is that the analytical results will not actually provide a measurement of what is in the water. If the composite sample turns out to be negative. It is possible that some VOCs may be present at trace levels

and will not be detected in a composite sample. Therefore, sample-compositing is not the preferred approach but one that can be used when monitoring costs add a significant economic burden, with recognition of its limitations.

Confirmation samples of positive results can be required by the State; results of confirmation samples must be included in the quarterly average along with the initial sample. States, however, have discretion to delete obvious analytical errors in the initial or confirmation samples. In addition, States have discretion to require additional monitoring samples; results of all samples must be included in each respective quarterly average (except as noted above for obvious errors).

EPA modified some of the monitoring requirements it proposed in the November 1985 notice to address the concern of many commenters regarding monitoring costs. These changes are summarized below and further discussed in the Methods and Monitoring document (Ref. 1).

(1) The number of samples required for ground and surface water systems has been reduced from the number proposed. The rule allows composite samples of multiple sampling sites (up to five samples), resulting in lower costs. When monitoring costs would create an unacceptable financial burden, States that conduct the monitoring themselves can composite samples from different systems. This may be particularly beneficial for monitoring non-transient non-community water systems. As proposed, under the final rule, if VOCs are detected in a composite sample, follow-up analysis is required for each source (see discussion of composite samples).

(2) The repeat compliance monitoring requirements for those systems that the State determines are vulnerable but in which no VOCs were found in the initial sample, are based upon system size (see Table 4).

(3) For systems finding two-carbon VOCs, vinyl chloride analysis is required. If vinyl chloride is not detected in the initial sample States can reduce monitoring frequencies to once every three years for vinyl chloride.

As for comments recommending that EPA reduce sampling for systems with wells that only operate a few months a year, the Agency believes that any such reduction is appropriate. Under this final rule monitoring is required for all wells, including backup wells, only when they are being used. For example, four quarterly samples would not be required for wells that are only used for say two months per year; however, a sample each quarter that the wells operate would be needed.

The Agency agrees with the recommendation that the State make a vulnerability assessment once every three years rather than every year as proposed. In addition, EPA believes that the State should make a vulnerability assessment (≤ 500 connections) every five years only. These changes are reasonable because it is unlikely that significant undetected changes would occur in the vulnerability of a system sufficient to result in sufficient VOC contamination within a one- to two-year time period. The final rule reflects these changes.

EPA also proposed the following method for determining compliance:

(1) All quarterly compliance samples would be collected on the same day and analyzed according to procedures promulgated in this rule.

(2) Compliance with the MCL would be computed by running arithmetical average of the past four quarterly samples.

(3) Compliance would be determined for each sampling location; if water at that location was above the MCL, the entire system would be deemed out of compliance and public notice would be sent to all customers served by the system unless there was inter-mixing of