Part III

Environmental Protection Agency

40 CFR Parts 141 and 142
National Primary Drinking Water
Regulations; Synthetic Organic Chemicals
and Inorganic Chemicals; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH–FRL–4137–3]

Drinking Water; National Primary Drinking Water Regulations—Synthetic Organic Chemicals and Inorganic Chemicals; National Primary Drinking Water Regulations Implementation

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: By this document, EPA is promulgating maximum contaminant level goals (MCLGs) and National Primary Drinking Water Regulations (NPDWRs) for 18 synthetic organic chemicals (SOCs) and 5 inorganic chemicals (IOCs). The NPDWRs consist of maximum contaminant levels (MCLs) for the SOCs and IOCs. The NPDWRs also include monitoring, reporting, and public notification requirements for these chemicals. Regulation of sulfate, one of the contaminants in the proposed rule, has been deferred. This document includes the best available technology (BAT) upon which the MCLs are based and the BAT for the purpose of issuing variances.

DATES: The effective date for revisions and additions to §§ 141.32, 141.40, 141.50 (except 141.50(b)(26)), 141.51 141.61 (except 141.61(c)(26)), 141.62, 142.16, and 142.62 is January 17, 1994. The effective date for revisions and additions to §§ 141.2, 141.6, 141.12, 141.23, 141.24, 141.50(b)(26), 141.60, 141.61(c)(26), and 141.89 is August 17, 1992. In accordance with 40 CFR 23.7, this regulation shall be considered final Agency action for the purposes of judicial review at 1 p.m., Eastern time on July 31, 1992.

ADDRESSES: Copies of the public comments received, EPA responses, and all other supporting documents (including references included in this notice) are available for review at the U.S. Environmental Protection Agency (EPA), Drinking Water Docket, 401 M Street, SW., Washington, DC 20460. For access to the docket materials, call 202–260–3027 between 9 a.m. and 3:30 p.m. Any document referenced by an MRID number is available by contacting Susan Lawrence, Freedom of Information Office, Office of Pesticide Programs, at 703–557–4454.

Copies of health criteria, analytical methods, and economic impact analysis documents are available for a fee from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800–336–4700, local: 703–487–4650. Additionally, they can be reviewed at the EPA regional offices listed below.

FOR FURTHER INFORMATION CONTACT: Gregory Helms, Regulation Management Branch, Drinking Water Standards Division, Office of Ground Water and Drinking Water (WH–550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202–260–8049, or one of the EPA Regional Office contacts listed below. General information may also be obtained from the EPA Drinking Water Hotline. Callers within the United States may reach the Safe Drinking Water Hotline at 800–426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4 p.m. Eastern Time.

EPA Regional Offices

I. JFK Federal Bldg., Room 2203, One Congress Street, 11th floor, Boston, MA 02203, Phone: (617) 565–3610, Jerry Healey
II. 26 Federal Plaza, Room 824, New York, NY 10278, Phone: (212) 264–1800, Walter Andrews
III. 841 Chestnut Street, Philadelphia, PA 19107, Phone: (215) 597–9800, Dale Long
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IX. 75 Hawthorne Street, San Francisco, CA 94105, Phone: (415) 744–1855, Steve Pardieck
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SUPPLEMENTARY INFORMATION:

Table of Contents

Abbreviations Used in this Rule List of Tables

Abbreviations Used in This Rule

AA: Direct Aspiration Atomic Absorption Spectroscopy
ACS: American Chemical Society
ADI: Acceptable Daily Intake
ASDWA: Association of State Drinking Water Administrators
ASTM: American Society for Testing Materials
BAT: Best Available Technology
BTGA: Best Technology Generally Available
CRAVE: Cancer Risk Assessment Verification Enterprise
CAA: Clean Air Act
CAG: Cancer Assessment Group
CUR: Carbon Usage Rate
CWS: Community Water System
DWEL: Drinking Water Equivalent Level
EBCT: Empty Bed Contact Time
EIA: Economic Impact Analysis
EMSL: Environmental Monitoring Systems Laboratory (Cincinnati)
EPA: Environmental Protection Agency
FDA: Food and Drug Administration
FR: Federal Register
GAC: Granular Activated Carbon
GFAA: Graphite Furnance Atomic Absorption Spectroscopy
HPLC: High Pressure Liquid Chromatography
HSDB: Hazardous Substances Data Base
ICP–AES: Inductively Coupled Plasma-Atomic Emission Spectroscopy
IE: Ion Exchange
IMDL: Inter-Laboratory Method Detection Limit
IOC: Inorganic Chemical
IRIS: Integrated Risk Information System
LOAEL: Lowest-Observed-Adverse-Effect Level
LOQ: Limit of Quantitation
MCAWW: Methods for Chemical Analysis of Water and Wastes
MCL: Maximum Contaminant Level (expressed as mg/1)[1]
MCLG: Maximum Contaminant Level Goal
MDL: Method Detection Limit
MF: Modifying Factor
MGD: Million Gallons per Day
NAS: National Academy of Sciences
NCWS: Non-Community Water System
NIPDWR: National Interim Primary Drinking Water Regulation
NOA: Notice of Availability
NOAEL: No-Observed-Adverse-Effect Level
NOEL: No-Observed-Effect Level
NPDES: National Pollution Discharge Elimination System
NPDWR: National Primary Drinking Water Regulation
NTIS: National Technical Information Service
NTNCWS: Non-Transient Non-Community Water System
O&M: Operations & Maintenance
OPP: Office of Pesticide Programs
ORD: Office of Research and Development
OW: Office of Water
OX: Oxidation (Chlorine or Ozone)
PAC: Powdered Activated Carbon
PAHs: Polynuclear Aromatic Hydrocarbons
Pathco: Pathology Working Group
PE: Performance Evaluation
POE: Point-of-Entry Technologies
POU: Point-of-Use Technologies
PQL: Practical Quantitation Level
PTA: Packed Tower Aeration
PWS: Public Water System
RCRA: Resource Conservation Recovery Act
RfC: Reference Concentration
RfD: Reference Dose (formerly termed Acceptable Daily Intake (ADI))
RIA: Regulatory Impact Analysis
RMCL: Recommended Maximum Contaminant Level
RO: Reverse Osmosis
RSC: Relative Source Contribution
SDWA: Safe Drinking Water Act, or the "Act," as amended in 1986
SMCL: Secondary Maximum Contaminant Level
SMF: Standardized Monitoring Framework
SOC: Synthetic Organic Chemical
T&C: Technology & Costs
TEF: Toxic Equivalency Factors
TEM: Transmission Electron Microscopy
TWS: Transient Non-Community Water System
UF: Uncertainty Factor
UIC: Underground Injection Control
USDA: U.S. Department of Agriculture
VOC: Volatile Organic Chemcial
WHP: Wellhead Protection
WHPA: Wellhead Protection Area
WS: Water Supply

[1] 1,000 micrograms (µg) = 1 milligram (mg).

List of Tables

Table 25—Increased Cost of Compliance in Selected System Size Categories

I. Summary of Today's Action

TABLE 1.—MCLGs AND MCLs FOR INORGANIC CONTAMINANTS

Chemical	Proposed MCLGs (mg/l)	Final MCLGs (mg/l)	Proposed MCLs (mg/l)	Final MCLs (mg/l)
(1) Antimony	0.003	0.006	[1]0.01/0.005	0.006
(2) Beryllium	Zero	0.004	0.001	0.004
(3) Cyanide	0.2	0.2	0.2	0.2
(4) Nickel	0.1	0.1	0.1	0.1
(5) Sulfate	[1]400/500	Deferred	400/500 [1]	Deferred
(6) Thallium	0.0005	0.0005	[1]0.002/0.001	0.002

[1] Alternative MCLG/MCL options were proposed in the July 25, 1990 notice.

TABLE 2.—MCLGs AND MCLs FOR ORGANIC CONTAMINANTS

Chemical	Proposed MCLGs (mg/l)	Final MCLGs (mg/l)	Proposed MCLs (mg/l)	Final MCLs (mg/l)
VOCs:				
Dichloromethane	Zero	Zero	0.005	0.005
1,2,4-Trichlorobenzene	0.009	0.07	0.009	0.07
1,1,2-Trichloroethane	0.003	0.003	0.005	0.005
Pesticides:				
Dalapon	0.2	0.2	0.2	0.2
Dinoseb	0.007	0.007	0.007	0.007
Diquat	0.02	0.02	0.02	0.02
Endothall	0.1	0.1	0.1	0.1
Endrin	0.002	0.002	0.002	0.002
Glyphosate	0.7	0.7	0.7	0.7
Oxamyl (Vydate)	0.2	0.2	0.2	0.2
Picloram	0.5	0.5	0.5	0.5
Simazine	0.001	0.004	0.001	0.004
Other organic contaminants:				
Benzo(a)pyrene	Zero	Zero	0.0002	0.0002
Di(2-ethylhexyl)adipate	0.5	0.4	0.5	0.4
Di(2-ethylhexyl)phthalate	Zero	Zero	0.004	0.006
Hexachlorobenzene	Zero	Zero	0.001	0.001
Hexachlorocyclopentadiene	0.05	0.05	0.05	0.05
2,3,7,8-TCDD (Dioxin)	Zero	Zero	5×10^{-8}	3×10^{-8}

TABLE 3—BEST AVAILABLE TECHNOLOGIES TO REMOVE INORGANIC CONTAMINANTS

Inorganic contaminant	Best available technologies						
	Activated alumina	Coagulation/ filtration	Lime softening [1]	Ion exchange	Reverse osmosis	Chlorine oxidation	Electrodialysis
Antimony		X			X		
Beryllium	X	X	X	X	X		
Cyanide				X	X	X	
Nickel			X	X	X		
Thallium	X			X	X		

[1] Not 1415 BAT for small systems for variances unless treatment is currently in place.

TABLE 4—BEST AVAILABLE TECHNOLOGIES TO REMOVE SYNTHETIC ORGANIC CONTAMINANTS

Chemical	GAC [1]	PTA [2]	OX [3]
VOCs:			
Dichloromethane		X	
1,2,4-Trichlorobenzene	X	X	
1,1,2-Trichloroethane	X	X	
Pesticides:			
Dalapon	X		
Dinoseb	X		
Diquat	X		
Endothall	X		
Endrin	X		
Glyphosate			X
Oxamyl (Vydate)	X		
Picloram	X		

TABLE 4—BEST AVAILABLE TECHNOLOGIES TO REMOVE SYNTHETIC ORGANIC CONTAMINANTS—Continued

Chemical	GAC [1]	PTA [2]	OX [3]
Simazine	X		
Other Organic Contaminants.			
Benzo(a)pyrene	X		
Di(2-ethylhexyl)adipate	X	X	
Di(2-ethylhexyl)phthalate	X		
Hexachlorobenzene	X		
Hexachlorocyclopentadiene	X	X	
2,3,7,8-TCDD (Dioxin)	X		

[1] GAC = Granular activated carbon.
[2] PTA = Packed tower aeration.
[3] OX = Oxidation (Chlorine or Ozone).

TABLE 5.—COMPLIANCE MONITORING REQUIREMENTS [1]

Contaminant	Base requirement		Trigger that increases monitoring	Waivers [2]
	Ground water	Surface water		
4 Inorganics	1 Sample/3 years	Annual sample	MCL	Yes, based on analytical results of 3 rounds.
	1 Sample/9 years after 3 samples <MCL			
Cyanide	1 Sample/3 years	Annual sample	>MCL	Yes, based on vulnerability assessment.
	1 Sample/9 years after 3 samples <MCL			
3 VOCs	([3])	([3])	<0.0005 mg/l	Yes, based on vulnerability assessment.
15 Pesticides/SOCs	([3])	([4])	Detection (as specified in the rule).	Yes, based on vulnerability assessment.

[1] The compliance monitoring requirements apply to community water systems and non-transient non-community water systems.
[2] Two types of waivers are available: waivers by rule and vulnerability waivers. Waivers by rule are based on prior monitoring results. They reduce but do not eliminate monitoring. Vulnerability waivers eliminate monitoring for pesticides and will reduce monitoring requirements for volatile organic contaminants, but must be renewed, usually every three years (see Section III.C for additional information).
[3] Quarterly/year; annual after one year of no detect; every 3 years after 3 rounds
[4] 4 quarterly samples every 3 years; after 1 round of no detect: systems 3,300 reduce to 2 samples/year every 3 years, systems <3,300 reduce to 1 sample every 3 years

TABLE 6.—ANALYTICAL METHODS FOR INORGANIC CHEMICALS

Contaminant	Methodology [1]
Antimony	Atomic absorption; furnace inductively-coupled plasma-mass spectrometry, hydride-atomic absorption.
Beryllium	Atomic absorption; furnace inductively-coupled plasma, inductively coupled plasma-mass spectrometry.
Cyanide [3]	Distillation, spectrophotometric [5] distillation, automated, spectrophotometric [2], distillation, selective electrode [2], distillation, amenable, spectrophotometric [4].
Nickel	Atomic absorption; furnace inductively-coupled plasma, inductively-coupled plasma-mass spectrometry.
Thallium	Atomic absorption; furnace inductively-coupled plasma-mass spectrometry.

[1] See rule for specific references.
[2] Screening method for total cyanides.
[3] MCLG/MCL applies to "free" cyanides.
[4] Measures amenable or "free" cyanides.

TABLE 7.—ANALYTICAL METHODS FOR VOLATILE ORGANIC CHEMICALS

Contaminant	EPA methods
Dichloromethane	502.1, 502.2, 524.1, 524.2.
1,2,4-Trichlorobenzene	502.2, 503.1, 524.2.

TABLE 7.—ANALYTICAL METHODS FOR VOLATILE ORGANIC CHEMICALS—Continued

Contaminant	EPA methods
1,1,2-Trichloroethane	502.1, 502.2, 524.1, 524.2.

TABLE 8.—ANALYTICAL METHODS FOR PESTICIDES/SOCs

EPA methods	Contaminants
505	Endrin. Hexachlorobenzene. Hexachlorocyclopentadiene. Simazine.
506	Di (2-ethylhexyl) adipate. Di (2-ethylhexyl) phthalate.
507	Simazine.
508	Endrin. Hexachlorobenzene.
515.1	Dalapon. Dinoseb. Picloram.
531.1	Oxamyl (Vydate).
1613	2,3,7,8-TCDD (Dioxin).
547	Glyphosate.
548	Endothall.
549	Diquat.
550/550.1	Benzo (a) pyrene.

TABLE 8.—ANALYTICAL METHODS FOR PESTICIDES/SOCs—Continued

EPA methods	Contaminants
[1]525.1	Benzo (a) pyrene. Di (2-ethylhexyl) adipate. Di (2-ethylhexyl) phthalate. Endrin. Hexachlorobenzene. Hexachlorocyclopentadiene. Simazine.

[1] Method 525.1 may be used if adequate sensitivity is demonstrated. See Section IIIB for additional information.

TABLE 9.—LABORATORY CERTIFICATION CRITERIA

IOCs:	
Antimony	±30% at ≥ 0.006 mg/l.
Beryllium	±15% at ≥ 0.001 mg/l.
Cyanide	±25% at ≥ 0.1 mg/l.
Nickel	±15% at ≥ 0.01 mg/l.
Thallium	±30% at ≥ 0.002 mg/l.
VOCs:	
	±20% at ≥ 0.01 mg/l.
	±40% at < 0.01 mg/l.
SOCs:	
Endrin	±30%.
All other SOCs	2 standard deviations based on study statistics.

II. Background

A. Statutory Authority

These regulations are among a continuing series of rules mandated by the 1986 Amendments to the Safe Drinking Water Act. As this final rule demonstrates, EPA is committed to effective implementation of the laws established by Congress. It should be noted that EPA's development and promulgation of these rules is now being coordinated with a number of other EPA activities intended to ensure protection of public health while responsibly addressing the economic challenge of the ever-growing list of regulatory requirements on States and water systems. To the extent that the results of this coordination call for change in the law, we will make that known to the Congress. It is a commitment of EPA, however, to understand where legitimate local implementation concerns exist.

EPA is working with a recently convened Governors' Forum on Environmental Management that is reviewing means to ensure health protection while balancing the need for State regulatory flexibility to address the States' highest priorities with available resources. EPA's Environmental Financial Advisory Board is developing alternative financing mechanisms with particular attention on small community concerns. In addition, EPA is in the third year of an initiative to identify and promote low-cost solutions to drinking water protection. These include consolidation of water systems to spread costs over a larger consumer base; pooling of several systems' water samples to reduce monitoring cost; and low-cost treatment technologies that can cut water bills in very small water systems to as much as one-half what might arise with traditional engineering solutions.

In addition, EPA is considering greater reliance on risk-based priority-setting within State compliance programs. That approach would focus limited State and Federal resources on those elements of the public water supply supervision program having the greatest potential for reducing risk and promoting public health protection. Again, EPA would only take action in this area to the extent consistent with law.

The Safe Drinking Water Act (SDWA or "the Act"), as amended in 1986 (Pub. L. 99-339, 100 Stat. 642), requires EPA to publish "maximum contaminant level goals" (MCLGs) for contaminants which, in the judgment of the Administrator, "may have any adverse effect on the health of persons and which [are] known or anticipated to occur in public water systems" (section 1412(b)(3)(A)). MCLGs are to be set at a level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" (section 1412(b)(4)).

At the same time EPA publishes an MCLG, which is a non-enforceable health goal, it must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either (1) a maximum contaminant level (MCL), or (2) a required treatment technique (section 1401(1), 1412(a)(3), and 1412(b)(7)(A)). A treatment technique may be set only if it is not "economically or technologically feasible" to ascertain the level of a contaminant (Sections 1401(1) and 1412(b)(7)(A)). An MCL must be set as close to the MCLG as feasible (section 1412(b)(4)). Under the Act, "feasible" means "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 (taking cost into consideration)" (section 1412(b)(5)). In setting MCLs, EPA considers the cost of treatment technology to large public water systems with relatively clean source water supplies [132 Cong. Rec. S6287 (daily ed., May 21, 1986)].[1] Each NPDWR that establishes an MCL must list the best available technology, treatment techniques, and other means that are feasible for meeting the MCL (BAT) (section 1412(b)(6)). NPDWRs include monitoring, analytical and quality assurance requirements, specifically, "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels * * * " (section 1401(1)(D)). Section 1445 also authorizes EPA to promulgate monitoring requirements.

Section 1414(c) requires each owner or operator of a public water system to give notice to persons served by it of (1) any failure to comply with a maximum contaminant level, treatment technique, or testing procedure required by a NPDWR; (2) any failure to comply with any monitoring required pursuant to section 1445 of the Act; (3) the existence of a variance or exemption; and (4) any failure to comply with the requirements of any schedule prescribed pursuant to a variance or exemption.

Under the 1986 Amendments to the SDWA, EPA was to complete the promulgation of NPDWRs for 83 listed contaminants, in three phases, by June 19, 1989. After 1989, an additional 25

contaminants must be regulated every three years (section 1412(b)).

In the 1986 Amendments to the SDWA, Congress required that MCLGs and MCLs be proposed and promulgated simultaneously (section 1412(a)(3)). This change streamlined development of drinking water standards by combining two steps in the regulation development process. Section 1412(a)(2) renamed recommended maximum contaminant levels (RMCLs) as maximum contaminant level goals (MCLGs).

B. Regulatory History

On June 25, 1990, EPA entered into a consent order with the Bull Run Coalition in response to a citizen suit. This consent order requires proposal for contaminants in today's notice by June 29, 1990 and promulgation by February 29, 1992. The promulgation date was extended to May 18, 1992. The promulgation of today's regulations partially fulfills the terms of the consent decree between EPA and the Bull Run Coalition.

On July 25, 1990, EPA proposed MCLGs and MCLs for 24 inorganic and organic chemical contaminants. Today's notice takes final action on 23 of those proposed regulations (excluding sulfate). Where today's rule promulgates MCLGs, MCLs, analytical methods, best available technology, monitoring requirements, and State implementation requirements that differ from the proposal, the changes result from public comments and/or additional data that were submitted during the comment period or which the preamble indicated were under development or analysis. The technical and/or policy basis for these changes are explained in this notice.

Section 1412(b)(1) of the SDWA directed EPA to publish MCLGs and promulgate NPDWRs for nine contaminants by June 19, 1987, for 40 additional contaminants by June 19, 1988, and for the rest of the 83 contaminants by June 19, 1989. The Agency has previously published MCLGs and promulgated NPDWRs for eight VOCs and fluoride by June 19, 1987 [see 52 FR 25690, 51 FR 11396, and 50 FR 47142]. On June 29, 1989, EPA finalized regulations for coliform and other microbiological contaminants [54 FR 27544 and 54 FR 27468]. Regulations for 38 inorganic and organic contaminants from the List of 83 were promulgated on January 30, 1991 [56 FR 3526], and on July 1, 1991 [56 FR 30266], and on June 7, 1991 [56 FR 26460] for lead and copper. The Agency also proposed regulations for radionuclides on July 18, 1991 [56 FR 33050]. Development of drinking water

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[1] EPA also evaluates the costs to smaller systems in its analysis of economic impacts.

standards is specifically required under the SDWA for 22 of the 23 contaminants in today's rule [see SDWA section 1412(b)(1), 42 U.S.C. 300g–1(b)(1)]. Hexachlorobenzene, although not on the statutory list of contaminants to be regulated, is being regulated because it has been found in drinking water and may cause adverse human health effects.

C. Applicability

The MCLs promulgated by today's rule apply to all community and non-transient non-community PWS.

D. Public Comments on the Proposal

EPA requested comments on all aspects of the July 25, 1990 proposal. A summary of the major comments and the Agency's response to the issues raised are presented in the following section. The Agency's detailed response to the comments received are presented in the document "Response to Comments Received on the Proposed Requirements for 24 Contaminants of July 25, 1990 and Notice of Availability of November 29, 1991," which is in the public docket for this rule.

EPA received approximately 138 comments on the proposed MCLGs and MCLs in the July 1990 proposal. These comments represented the views of 66 industrial/commercial groups, 25 State governments, 36 local governments and public water systems, 2 public interest groups, 3 Federal agencies, as well as comments from individual citizens and academic interests.

EPA held a public hearing on the proposed rule September 25, 1990 in Washington, DC. Six individuals representing three organizations made oral presentations at the public hearing. A transcript of the hearing is available in the docket [USEPA, 1990j].

EPA published a Notice of Availability (NOA) on November 29, 1991 for public review and comment on new information received by the Agency and analyses of the information, which was being considered in establishing final regulations for these contaminants.

EPA received approximately 34 comments on the NOA. These comments represented the views of 14 industrial/commercial groups, 10 State governments, and 10 local governments and public water systems.

III. Explanation of Today's Action

A. Establishment of MCLGs

Most of the MCLGs promulgated today are at the same level as proposed in July 1990. However, the MCLGs for antimony, beryllium, simazine, di(2-ethylhexyl)adipate and 1,2,4-

trichlorobenzene are different from those proposed in that notice. Changes result from public comments and/or new information received by the Agency. The change in the MCLG for antimony is due to a reevaluation of the relative source contribution based on public comments. The change in the MCLG for beryllium is due to a reevaluation of its categorization for setting the MCLG (i.e., EPA revised its classification from Category I to Category II based on public comments and reevaluation of the data). The MCLGs for simazine, di(2-ethylhexyl)adipate and 1,2,4-trichlorobenzene changed because new health information became available for these three compounds since the July 1990 proposal. The new health data and other information pertinent to this rule was made available to the public for review and comment in the November 1991 NOA [56 FR 60949]. A full explanation of these changes is included below in the sections for each specific contaminant. The draft health criteria documents prepared in support of the proposed rules have all been finalized and placed in the public docket and through NTIS, with the exception of documents for dioxin and sulfate. Dioxin is being regulated based on the information in the draft criteria document, pending Agency review of dioxin health effects. Regulation of sulfate has been deferred.

Most of the MCLs promulgated today are at the same level as proposed in July, 1990. The MCL for thallium, for which options of 0.002 mg/l and 0.001 mg/l were proposed, is being finalized as 0.002 mg/l. Based on additional analytic chemistry data presented in the NOA, the proposed dioxin MCL of 5×10^{-8} mg/l is being reduced to 3×10^{-8} mg/l in this final rule. The MCLG and MCL for sulfate are being deferred pending further study. The justification for this action is discussed in section III.B.5 of this notice. Sulfate will be addressed in a future action.

In today's rule, EPA is responding to the major issues raised by the public in reference to the July 1990 proposal [55 FR 30370] and the November 1991 NOA [56 FR 60949]. For EPA's complete response to all issues raised in comments on both the July 1990 and November 1991 notices, EPA refers the reader to the Comment/Response Document found in the Phase V docket [USEPA, 1992a].

1. How MCLGs Are Developed

MCLGs are set at concentration levels at which no known or anticipated adverse health effects occur, allowing for an adequate margin of safety. Establishment of an MCLG for each

specific contaminant depends on the evidence of carcinogenicity from drinking water exposure or the Agency's reference dose (RfD) based on noncarcinogenic data.

The cancer classification for a specific chemical and the reference dose are adopted by two different Agency groups. Decisions on cancer classifications are made by the Cancer Risk Assessment Verification Endeavor (CRAVE) Work Group, which is composed of representatives of various EPA program offices. Decisions on EPA RfDs (using non-cancer endpoints only) are made through the Agency RfD/RfC work group, also composed of representatives of various EPA program offices. Decisions by CRAVE and the RfD/RfC groups represent consensus on risk assessments for the Agency and can be used by the respective regulatory programs as the basis for regulatory decisions. Summaries of the decisions by these two groups are published in the Agency's Integrated Risk Information System (IRIS). This system can be accessed by the public by contacting Mike McLaughlin of DIALCOM, Inc. at 202–488–0550.

The RfD (expressed in mg/kg/day) is an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious health effects during a lifetime. The RfD is derived from a no-or lowest-observed-adverse-effect level (called a NOAEL or LOAEL, respectively) that has been identified from a subchronic or chronic scientific study of humans or animals. The NOAEL or LOAEL is then divided by uncertainty factor(s) to derive the RfD.

Uncertainty factors are used in order to estimate the comparable "no-effect" level for a larger heterogeneous human population. The use of uncertainty factors accounts for intra- and inter-species variability, the small number of animals tested compared to the size of the population, sensitive subpopulations and the possibility of synergistic action between chemicals (see 52 FR 25690 for further discussion on the use of uncertainty factors).

The use of an uncertainty factor (UF) is important in the derivation of the RfD. EPA has established certain guidelines (shown below) to determine how to apply uncertainty factors when establishing an RfD [USEPA, 1986].

Uncertainty Factors (UFs)

• Use a 1- to 10-fold factor when extrapolating from valid experimental results from studies using prolonged

exposure to average healthy humans. This factor is intended to account for the variation in sensitivity among the members of the human population.

• Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty in extrapolating animal data to the case of humans.

• Use an additional 10-fold factor when extrapolating from less than chronic results on experimental animals where there are no useful long-term human data. This factor is intended to account for the uncertainty in extrapolating from less than chronic NOAELs to chronic NOAELs.

• Use an additional 10-fold factor when deriving a RfD from a LOAEL

instead of a NOAEL. This factor is intended to account for the uncertainty in extrapolating from LOAELs to NOAELs.

An additional uncertainty factor may be used according to scientific judgment when justified.

• Use professional judgment to determine another uncertainty factor (also called a modifying factor, MF) that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated above, e.g., the completeness of the overall data base and the number of species tested. The default value for the MF is 1.

From the RfD, a drinking water equivalent level (DWEL) is calculated. The DWEL represents the drinking water lifetime exposure at which

adverse health effects are not expected to occur over a lifetime. The DWEL is calculated by multiplying the RfD by an assumed adult body weight (generally 70 kg) and then dividing by an average daily water consumption of 2 liters per day [NAS, 1977]. The DWEL assumes the total daily exposure to a substance is from drinking water exposure. The MCLG is determined by multiplying the DWEL by the percentage of the total daily exposure expected to be contributed by drinking water, called the relative source contribution. Generally, EPA assumes that the relative source contribution form drinking water is 20 percent of the total exposure, unless other exposure data for the chemical are available [see 54 FR 22069 and 56 FR 3535]. The relative source contribution may be as high as 80 percent. The calculation below expresses the derivation of the MCLG:

$$RfD = \frac{NOAEL \ or \ LOAEL}{uncertainty \ factor(s)} = mg/kg \ body \ weight/day \quad (1)$$

$$DWEL = \frac{RfD \times body \ weight}{daily \ water \ consumption \ in \ l/day} = mg/l \quad (2)$$

$$MCLG = DWEL \times drinking \ water \ contribution = mg/l \quad (3)$$
$$(rounded \ to \ one \ significant \ figure)$$

For chemicals suspected to be carcinogenic to humans, the assessment for non-threshold toxicants consists of the weight of evidence of carcinogenicity in humans, using bioassays in animals and human epidemiological studies as well as information that provides indirect evidence (i.e., mutagenicity and other short-term test results). The objectives of the assessment are (1) to determine the level or strength of evidence that the substance is a human or animal carcinogen and (2) to provide an upperbound estimate of the possible risk of human exposure to the substance in drinking water. A summary of EPA's general carcinogen classification scheme is [USEPA, 1986]:

Group A—Human carcinogen based on sufficient evidence from epidemiological studies.

Group B1—Probable human carcinogen based on limited evidence of carcinogenicity in humans.

Group B2—Probable human carcinogen based on a combination of

sufficient evidence in animals and inadequate data in humans.

Group C—Possible human carcinogen based on limited evidence of carcinogenicity in animals in the absence of human data.

Group D—Not classifiable based on lack of data or inadequate evidence of carcinogenicity from animal data.

Group E—No evidence of carcinogenicity for humans (no evidence for carcinogenicity in at least two adequate animal tests in different species or in both epidemiological and animal studies).

EPA follows a three-category approach in developing MCLGs for drinking water contaminants (Table 10).

TABLE 10.—EPA'S THREE-CATEGORY APPROACH FOR ESTABLISHING MCLGs

Category	Evidence of carcinogenicity via drinking water	MCLG approach
I	Strong evidence considering weight of evidence, pharmacokinetics, potency and exposure.	Zero.
II	Limited evidence considering weight of evidence, pharmacokinetics, potency and exposure.	RfD approach with added safety margin of 1 to 10 or 10^{-5} to 10^{-6} cancer risk range.
III	Inadequate or no animal evidence.	RfD approach.

Each chemical is evaluated for evidence of carcinogenicity via ingestion. For volatile contaminants, inhalation data should also be considered. EPA takes into consideration the overall weight of evidence for carcinogenicity.

pharmacokinetics, potency and exposure.

EPA's policy is to set MCLGs for Category I chemicals at zero. The MCLG for Category II contaminants is calculated by using the RfD approach with an added margin of safety to account for possible cancer effects. If adequate data are not available to calculate an RfD, the MCLG is based on a cancer risk range of 10^{-5} to 10^{-6}. MCLGs for Category III contaminants are calculated using the RfD/DWEL approach.

The MCLG for Category I contaminants is set at zero because it is assumed, in the absence of other data, that there is no known threshold for carcinogenicity. Category I contaminants are those for which EPA has determined that there is strong evidence of carcinogenicity from drinking water. In the absence of other data (e.g., oral) on the potential cancer risk from drinking water ingestion, chemicals classified as Group A or B carcinogens are generally placed in Category I.

Category II contaminants include those contaminants which EPA has determined that there is limited evidence of carcinogenicity from drinking water considering weight of evidence, pharmacokinetics, potency and exposure. In the absence of ingestion data, chemicals classified by the Agency as Group C chemicals are generally placed in Category II. For Category II contaminants, two approaches are used to set the MCLG: Either (1) setting the MCLG based upon noncarcinogenic endpoints of toxicity (the RfD) then applying an additional safety factor of 1 to 10, or (2) setting the MCLG based upon a theoretical lifetime excess cancer risk range of 10^{-5} to 10^{-6} using a conservative mathematical extrapolation model. EPA generally uses the first approach; however, the second approach is used when valid noncarcinogenic data are not available to calculate an RfD and adequate experimental data are available to quantify the cancer risk.

EPA requested comment on the appropriateness of these approaches for establishing MCLGs in the July 25, 1990 proposal (see 55 FR 30404–05). Two comments were received on this issue. One commenter stated that the MCLGs and the MCLs should be set at levels able to protect against carcinogenic risk. The other commenter stated that Group C contaminants are not suitable for evaluation by EPA's cancer risk assessment process, and supported EPA's use of non-carcinogenic data for establishing the MCLG for these chemicals. EPA believes that the present

approach for Category II contaminants is protective of non-cancer effects as well as potential carcinogenic risk. Therefore, because adequate non-carcinogenic data are available, the MCLGs promulgated today for Category II contaminants (beryllium, di(2-ethylhexyl)adipate, simazine and 1,1,2-trichloroethane) use the first option, i.e., they are based on the RfD with an application of an additional safety factor.

Category III contaminants include those contaminants for which there is inadequate evidence of carcinogenicity from drinking water. If there is no additional information to consider, contaminants classified as Group D or E chemicals are generally placed in Category III. For these contaminants, the MCLG is established using the RfD approach.

2. Occurrence and Relative Source Contribution

Most of the comments received on occurrence/exposure and relative source contribution (RSC) were related to current EPA policy. The Agency has addressed many of the questions raised by these commenters in the Comment Response Document for this rule. Below is a summary of the major issues raised and EPA's response.

EPA received some comments questioning the need to regulate a chemical if there are little occurrence data available, if the chemical occurs infrequently or at low levels, or if the RSC is below 20 percent. The Agency has the statutory mandate, under Section 1412 of the SDWA, to regulate contaminants "which are known or anticipated to occur in public water systems." The Agency believes that the contaminants in today's rulemaking have either been found or potentially may occur in public water supplies and that they may pose a health risk to consumers. Also, development of drinking water standards is specifically required under the Safe Drinking Water Act (SDWA) for 22 of the 23 contaminants in today's rule (see SDWA Section 1412(b)(1), 42 U.S.C. 300g–1(b)(1)).

Several commenters questioned why EPA was regulating hexachlorobenzene, since it is not on the list of 83 contaminants nor on the Drinking Water Priority List (DWPL). Hexachlorobenzene, although neither on the statutory list of contaminants to be regulated nor on the DWPL, is being regulated because it has been found in drinking water and may cause adverse human health effects.

As described in the background occurrence document for

hexachlorobenzene [USEPA, 1989b], it has been widely detected in water, albeit at low levels. Of 1,053 observations of ground water in STORET, 1,026 samples had detectible (although not quantifiable) levels of hexachlorobenzene. In surface water STORET samples, 48 of 54 samples had detectible (although not quantifiable) levels of hexachlorobenzene. The potential for hexachlorobenzene occurrence in public water supplies is corroborated by more recent information reported in EPA's "National Survey of Pesticides in Drinking Water Wells" [USEPA, 1990i], which detected hexachlorobenzene in several samples and projected that 470 PWS wells (range 61–1,630 wells) may have detectible levels (the minimum reporting limit for the NPS was 0.060 μg/l). EPA therefore believes that although levels may be low, there is ample evidence to conclude that hexachlorobenzene is known or anticipated to occur in public water systems as required by the SDWA.

Several comments were received on the current policy related to the use of a 20 percent floor and 80 percent ceiling for the RSC in setting the MCLG. Some commenters objected to using a 20 percent floor and 80 percent ceiling for the RSC when actual data are available and suggested percent contributions above or below these levels. Others suggested using an RSC of less than 20 percent if available data indicate a drinking water contribution below this percentage, assuming 100 percent contribution from drinking water in the absence of data, and assuming 50 percent contribution from inorganics and some pesticides in the absence of data.

The Agency continues to believe the 20 percent floor and 80 percent ceiling are prudent and protective of public health. The 20 percent floor represents a level below which additional incremental protection is negligible. In addition, below 20 percent RSC from water is a clear indication that control of other more contaminated media will result in a significantly greater reduction in exposure. EPA believes the 80 percent ceiling is required because it ensures that the MCLG will be low enough to provide adequate protection for those individuals whose total exposure to a contaminant is higher than indicated by available data. This approach, in effect, results in a slightly lower MCLG and increases the margin of safety. EPA utilizes the actual percentage when adequate exposure data exist and indicate an RSC between 20 and 80 percent, but when data are not adequate, 20 percent is generally used

as a default value that is protective of public health. In addition, the Agency does not believe that assuming a 50 percent RSC is appropriate for inorganics or pesticides in the absence of data, as suggested by a commenter. In fact, there have been numerous inorganics (such as lead or mercury) and pesticides regulated by EPA in public drinking water supples for which the available data from all sources indicate that drinking water likely contributes less than 50 percent to total exposure and, in some cases, less than 20 percent. Therefore, there is no basis for automatically assuming 50 percent from drinking water when data are not available.

There were three chemical-specific issues regarding setting the RSC. One RSC issue concerned cyanide. Several commenters suggested the use of an 80 to 100 percent RSC because they felt that drinking water represents essentially all exposure. The Agency has decided to use a 20 percent RSC for this contaminant because the available data on dietary exposure are inadequate, and the Agency therefore could not adequately characterize overall exposure to cyanide.

Another commenter claimed that the Agency misinterpreted a USDA study [Miller-Ihli and Wolf, 1986] on the dietary intake, and that EPA should have used more appropriate data regarding intake of nickel from food and air to calculate the MCLG. The Agency agrees that the study relied upon in the proposed rule was inappropriate for calculating dietary exposure for nickel because that study analyzed foods that were freeze-dried, which resulted in elevated nickel concentrations (higher than one would determine in fresh foods). The Agency has recalculated the dietary contribution using an FDA diet study by Pennington and Jones (1987). Unlike the Miller-Ihli and Wolf study, which involved an analysis of freeze-dried foods, the Pennington Diet Study program [Pennington and Jones, 1987] is appropriate for estimating overall exposure. The revised calculation indicates again that drinking water contributes less than 20 percent of the daily intake. Therefore, the Agency is using 20 percent as the RSC in the calculation of the final MCLG for nickel following present policy of a 20 percent floor. Two commenters on the NOA urged EPA to revise the RSC for nickel and base a new RSC on analysis of actual data, as was done for antimony. As discussed above, EPA has done this and believes the available data, in conjunction with EPA's policy on RSC, supports the use of the 20 percent value.

The third issue is related to EPA's proposal to use a 20 percent RSC for antimony as a default value. The Agency agrees with the commenter that there is information available on which the RSC can appropriately be based. The Agency has decided to use an occurrence study by Greathouse and Craun (1978) and has estimated typical levels of 2 µg/l antimony in drinking water. This study was chosen due to its large sampling base and representativeness of antimony levels nationwide. The Agency has also recalculated the dietary intake of antimony using a different food study by Cunningham and Stroube (1987). The dietary contribution of 4.7 µg/day of antimony calculated from this study is lower than previously estimation. The Cunningham and Stroube report was judged adequate for determining the overall exposure estimation. This study, conducted by the FDA, uses the methodology of their Total Diet Study program [Cunningham and Stroube, 1987]. By using an inhalation contribution of 0.7 µg/day and the 4.7 µg/day from the diet, along with a mean drinking water contribution of 2 µg/l (or 4 µg/day), the resulting RSC is 40 percent (rounded from 42.6 percent). The NOA requested comment on revision of the antimony RSC, and several commenters supported the proposed revision. The final MCLG for antimony reflects this change in the RSC.

The Agency refers readers to the Comment Response Document [USEPA, 1992a] for additional detailed information on the issues discussed above, and for a discussion of other exposure/RSC related comments raised during the public comment period.

3. Inorganic MCLGs

a. *Antimony.* EPA proposed an MCLG of 0.003 mg/l for antimony in the July 25, 1990 proposal [55 FR 30377]. Antimony has been classified in Group D (inadequate evidence of carcinogenicity in humans) by EPA guidelines. The proposed MCLG was derived from a DWEL of 0.015 mg/l, applying a 20 percent contribution from drinking water. The MCLG was based upon a LOAEL of 0.43 mg/kg/day for noncarcinogenic effects in a lifetime drinking water study in rats [Schroeder et al., 1970]. An uncertainty factor of 1,000 was applied to the LOAEL derived from a lifetime animal study (which is in accordance with NAS/EPA guidelines).

No new toxicological data that would change the conclusions presented in the July 25, 1990 proposal have become available since its publication. However, the Agency has revised its calculation of the relative source

contribution for antimony after reconsidering the occurrence/exposure data, as discussed in the "Relative Source Contribution" section above. Based on this reassessment of the available occurrence/exposure data, the final RSC for antimony has been set at 40 percent. This change in the RSC results in a doubling of the final MCLG from 0.003 to 0.006 mg/l for antimony.

Public Comments: In response to the July 25, 1990 notice, one individual or organization commented on the MCLG proposal for antimony. The commenter indicated that an online computer search of the Hazardous Substances Data Base (HSDB) showed that antimony causes marked weight loss, hair loss, dry scaly skin, eosinophilia, myocardial failure, vomiting, diarrhea and stomatitis in animals orally exposed.

EPA Response: EPA agrees with the commenter that antimony causes the above mentioned effects when used in high doses in animal tests. These effects were discussed in the Health Criteria Document for antimony supporting the July 1990 proposal [USEPA, 1990d, finalized as USEPA, 1992b]. However, the effects reported in the July 1990 notice are effects associated with the critical endpoint of toxicity used to establish the lowest-observed-adverse-effect level (LOAEL) for antimony. The effects described by the commenter are acute effects noted at much higher dose levels than the dose causing the critical effects described in the July 1990 notice. Since the critical effects are the basis of the DWEL and MCLG calculations for antimony, only these effects were discussed in the July 1990 proposal. Detailed descriptions of antimony toxicity at different dose levels and in different animal species are documented in the Antimony Health Criteria Document prepared in support of the July 1990 notice [USEPA, 1990d, finalized in USEPA, 1992f]. This document is available in the EPA Public Docket, Office of Water. Based on the available toxicological information and on the relative source contribution reassessment, the Agency is promulgating today an MCLG of 0.006 mg/l for antimony.

b. *Beryllium.* EPA followed a Category I approach for beryllium and proposed an MCLG of zero for beryllium in drinking water [55 FR 30378] based on the evidence of carcinogenic potential from drinking water. The Agency requested comment on setting the MCLG at zero for beryllium given that the oral exposure bioassays are not adequate to conclusively demonstrate a dose-response relationship. Beryllium is

classified in Group B2, probable human carcinogen, based on the positive carcinogenic findings in several animal species exposed to beryllium by inhalation and injection. In addition, available data indicate tumor induction by several beryllium compounds and genotoxic activity in animal studies. Since the dose-response evidence of carcinogenicity specifically by ingestion is limited, the Agency requested public comments on setting the MCLG of beryllium at zero.

Public Comments: Eleven commenters responded to the beryllium proposal. One significant area of comment in response to the proposal deals with the carcinogenicity of beryllium via the oral route of exposure. The commenters disagreed with the Agency on the classification of beryllium in Group B2. The commenters stated that cancer studies performed with beryllium sulfate in drinking water [Schroeder et al., 1970] or in feed [Morgareidge, 1977] are inadequate because the tumors observed in these studies were statistically not significant when compared with those in controls. One commenter suggested that since statistical significance was not observed in these studies, beryllium should be classified as a Group C carcinogen and the MCLG should be recalculated using the options for Group C compounds. The commenter stated that the Agency has been inconsistent in its proposed regulation for beryllium in drinking water because MCLGs have been set at non-zero levels for nickel, chromium, cadmium, antimony and asbestos, which are classified by the Agency in Group A or B, via inhalation but in Group C or D by the oral route.

In addition, one commenter sent two additional studies of beryllium toxicity to EPA during the comment period for the November 29, 1991 NOA.

EPA Response: EPA establishes MCLGs for drinking water contaminants by placing them in three categories, as discussed above. With regard to the oral carcinogenicity of beryllium, EPA has reconsidered the data and agrees with the comments regarding the oral beryllium studies in that the induction of tumors was statistically not significant when compared with the controls. However, the Agency believes that these studies show a suggestive tumorigenic response which are consistent with the hazard seen in other portions of the beryllium data base. In the July 1990 proposal, the Agency indicated that these studies were limited in their usefulness to evaluate carcinogenic potential in animals because the Schroeder et al. study (1970)

used only one dose, and the Morgareidge study did not reflect a traditional dose-response relationship. In the Morgareidge study, there was an increase in reticulocyte tumors in rats at 5 and 50 ppm but not at 500 ppm. Taken together, the available studies show a limited carcinogenic potential from drinking water ingestion. This may relate in part to poor absorption of beryllium from ingestion. It has been postulated that ingested beryllium is precipitated in the gastrointestinal tract as beryllium phosphate, making it inaccessible for absorption.

In general, the mechanisms of absorption of metallic ions are not well understood and do not follow a dose-response relationship. On the other hand, there is clear evidence of carcinogenicity of beryllium via inhalation or injection in monkeys, rats and rabbits. Studies in animal species exposed to beryllium by inhalation or injection showed tumors at sites different from the route of exposure [IRIS, 1989]. Because beryllim produces tumors in several species (rats, monkeys, and rabbits) via inhalation or injection, the Agency has concluded that the overall weight of evidence provides sufficient evidence of carcinogenicity; therefore beryllium is classified by the Agency in Group B2 as discussed in the proposal. However, EPA has also placed beryllium in drinking water Category II (rather than Category I, as proposed) for regulation.

In response to public comments, EPA reevaluated the categorization of beryllium by reconsidering its potency, exposure, and pharmacokinetics. EPA changed its categorization of beryllium from Category I to Category II based on several factors. This contaminant is poorly absorbed from the gastrointestinal tract, and the majority of the ingested beryllium passes through the gut unabsorbed with less than one percent being absorbed. Also it is noted that, while the carcinogenic potential for beryllium is viewed as Group B2 based on the overall weight of evidence of the inhalation and ingestion data, the dose-response analysis for ingestion exposure does not provide adequate evidence of carcinogenicity from a drinking water source, as is true with many of the other B2 contaminants. Therefore, in setting an MCLG for beryllium in drinking water, EPA believes that a Category II approach (which includes a safety factor for possible carcinogenic potential) is appropriate based on the weight of evidence for carcinogenicity via ingestion, and also based on the potency, exposure and pharmacokinetics of this chemical. EPA

believes that these factors justify changing the categorization of beryllium from Category I to Category II.

For Category II contaminants, EPA generally sets the MCLG based upon noncarcinogenic endpoints (using the RfD approach) with a safety factor ranging from 1 to 10 applied to account for possible carcinogenicity. As stated in the July 1990 notice (55 FR 30378), EPA selected a lifetime oral study in rats (Schroeder et al., 1970) to derive the RfD and the DWEL for beryllium. An RfD of 0.005 mg/kg/day was derived from this study using an uncertainty factor of 100 (per NAS/EPA guidelines for use with a chronic study). This results in a DWEL of 0.2 mg/l and an MCLG of 0.004 mg/l. The derivation of the beryllium MCLG is given below:

$$DWEL = \frac{0.5 \text{ mg/kg/day} \times 70 \text{ kg}}{100 \times 2 \text{ liters/day}} = 0.2 \text{ mg/l}$$

$$MCLG = \frac{0.2 \text{ mg/l}}{10} \times 0.2 = 0.004 \text{ mg/l}$$

The DWEL is based on a 70-kg adult consuming 2 liters of drinking water per day. The MCLG includes an additional safety factor of 10 to account for possible carcinogenic potential of this contaminant via ingestion and assumes a drinking water contribution to total intake of 20 percent.

The Agency disagrees with the comment alleging inconsistencies with other drinking water regulations. To set regulations (including those for nickel, cadmium, chromium, antimony, and asbestos, as well as the MCLG for beryllium), each contaminant was evaluated independently to assess the available health effects data for drinking water. EPA considered the overall weight of evidence to determine carcinogenic potential. The factors considered included carcinogenic potential by ingestion in addition to other factors, e.g., cancer potency, pharmacokinetics, and exposure. The above inorganic contaminants are all classified in Group A or B according to the Agency's classification scheme, but were placed into different drinking water categories from those that would typically apply to the particular classifications. The commenter is mistaken that EPA classified these contaminants as Group C or D carcinogens by the oral route of exposure. Asbestos (cancer classification A) was placed in drinking water Category II due to limited evidence of carcinogenicity from drinking water; cadmium (cancer classification B1) was assigned to

drinking water Category III due to lack of evidence of carcinogenicity from drinking water (56 FR 3536). MCLGs for chromium (as chromium VI) (56 FR 3537) and nickel (as refinery dust) (55 FR 30382) (proposed), both belonging to cancer classification A based on the inhalation route of exposure, were set following a Category III approach since data by the oral route show no evidence of carcinogenicity. In short, a case-by-case decision on the categorization of a contaminant with respect to its carcinogenicity from drinking water ingestion is made based on the strength and overall weight of evidence.

EPA also received two health effects studies on beryllium submitted during the December 1991 NOA comment period. The comment period for beryllium closed in October 1990. No additional comments were solicited on beryllium during the NOA period. In addition, both studies do not appear to be peer-reviewed as published. Results of a preliminary review of these studies do not indicate they would lead to a change in the RfD or MCLG for beryllium.

One of the studies, by Morgareidge (1976), reported that in dogs, a maximum tolerated dose was likely just above 1 mg/kg/day, a level higher than the 0.54 mg/kg/day NOAEL from the Schroeder et al. (1970) study above. The other study, by Ward et al. (undated), is an epidemiology study of beryllium workers which presents no dose response information.

Consequently, after review of the timely public comments and a reassessment of the information on cancer and other toxicity concerns, EPA is placing beryllium in Category II for the reasons stated above, and promulgating an MCLG of 0.004 mg/l.

c. *Cyanide.* EPA followed a Category III approach and proposed an MCLG of 0.2 mg CN$^-$/l for cyanide in the July 25, 1990 proposal [55 FR 30379]. The Agency has classified cyanide in Group D since there are insufficient human and animal studies for an assessment of its carcinogenicity. A DWEL of 0.76 mg CN$^-$/l was derived using a NOAEL value of 10.8 mg CN$^-$/kg/day from a two-year dietary study in which rats were administered diets containing hydrogen cyanide [Howard and Hanzal, 1955]. In calculating the DWEL, an uncertainty factor of 100 was applied (in accordance with NAS/EPA guidelines for a lifetime animal study). An additional modifying factor of 5 was used to account for the possibility that cyanide would be absorbed more readily from drinking water than from food. The 0.2 mg CN$^-$/l proposed MCLG is a rounded value (from 0.15 mg CN$^-$/l)

derived from the DWEL and assuming a relative source contribution of 20% due to exposure from drinking water.

Public Comments: A total of eight individuals or organizations provided comments in response to the MCLG proposal regarding cyanide. Six commenters raised the issue of cyanide speciation. These commenters stated that while the proposed MCLG is based on "free cyanides," the proposed analytical methods imply that "total cyanides" will be regulated. While "free cyanides" are readily bioavailable and extremely toxic, "total cyanides" contain all cyanides, including those low-toxicity, inert species that are undissociable (to CN$^-$) and not absorbable (see the Analytical Methods Section for additional information).

Two commenters questioned the appropriateness of the NOAEL (10.8 mg CN$^-$/kg/day) that was selected for the MCLG calculation. One commenter suggested that the study by Howard and Hanzal (1955) is not preferable since no effects were observed in rats at the highest test dose level of 10.8 mg CN$^-$/kg/day, and studies should be designed to show an effect at the highest dose tested. Thus, this commenter claims that no NOAEL was identified. The other commenter stated that the rat LD$_{50}$ (reported range of 1–4 mg CN$^-$/kg) is lower than the NOAEL(10.8 mg CN$^-$/kg/day) used in the MCLG calculation. The commenter questioned whether the proposed MCLG will pose an acute hazard if a large amount of water was ingested at one time. Also, two commenters questioned the necessity of using a modifying factor of 5 in the derivation of the MCLG since the actual bioavailability of cyanide was not measured upon oral exposure through diet or drinking water.

EPA Response: In response to the comments concerning cyanide speciation, EPA is promulgating today an MCLG and MCL for cyanide that apply only to free cyanide. The Agency agrees with the commenters that only free cyanides should be regulated because these are the species of health concern due to their bioavailability and toxicity. The analytical methods issue is fully addressed in the Analytical Methods section of this rule. In summary, EPA is specifying the use of the "cyanide amendable to chlorination" test for determining the "free cyanide" concentrations, while the "total cyanide" analytical technique is being allowed to screen samples. If the "total cyanide" results are greater than the MCL, then the analysis for free cyanide would be required to determine whether there is an exceedance of the MCL.

EPA considers the NOAEL selected to be appropriate and to be protective against adverse health effects over a lifetime of exposure. The selection of a NOAEL of 10.8 mg CN$^-$/kg/day is based on sensitive endpoint of toxicity and is consistent with a study that found a NOAEL of 30 mg/kg CN$^-$ per day for weight loss, thyroid effects, and myelin degeneration in rats reported in a 11.5-month dietary study using KCN [Philbrick et al., 1979]. The commenter noted that the reported low LD$_{50}$ in rats, was lower than the selected NOAEL. However, the rat lethal dose of cyanide was an acute effect obtained by administering cyanide in bolus form by gavage. The NOAEL chosen is from a two-year chronic dietary study. Studies have shown that rats (and humans) can tolerate higher doses of cyanide (80 mg CN$^-$/kg/day) when mixed in the diet [Kreutler et al., 1978] than when administered in bolus form by gavage in aqueous solution (LD$_{50}$=4 mg CN$^-$/kg/day) [Ferguson, 1962]. Rats also tolerated a higher oral dose of cyanide (12 mg CN$^-$/kg/day for 21 days that was administered in drinking water; Palmer and Olson, 1979). The intermittent ingestion of low doses over a day would allow for sufficient detoxification.

Using the NOAEL chosen, an uncertainty factor of 500 was used in the calculation of the DWEL. This includes an uncertainty factor of 100 (for use of a NOAEL derived from a Chronic Study) and a 5-fold modifying factor to account for the fact that the NOAEL is from a dietary study.

The fatal oral dose of cyanide in humans reported by several investigators ranged from 0.5 to 3.5 mg/kg CN$^-$. The LD^{50} values and LOAELs for various acute (1–14 days) and subacute (90 days) effects in tested animals were reported in the same range as the human lethal levels or higher [USEPA, 1988b, finalized as USEPA, 1992h]. Assuming an average human body weight of 70 kg, the approximate fatal dose of CN$^-$ would be no less than 35 mg (0.5 mg/kg×70 kg). At the final MCL of 0.2 mg/l promulgated today, a person would need to ingest 175 liters of water (35 mg ÷ 0.2 mg/l) in one short time interval to obtain an acutely toxic dose, an unrealistic volume to consume. Therefore, EPA believes the derived MCLG is protective of both acute and chronic toxic effects of cyanide in drinking water.

After review of the comments, the Agency believes that the proposed MCLG is supported by the available health data and is promulgating today an MCLG of 0.2 mg/l for free cyanide.

d. *Nickel.* On July 25, 1990, EPA proposed an MCLG of 0.1 mg/l for nickel [55 FR 30381]. The MCLG was based on the Ambrose et al. 1976 study where rats were fed nickel sulfate hexahydrate in their diet for 2 years. Effects noted in the animals included decreased body weight in male and female rats, as well as increased relative heart weight and decreased relative liver weight in female rats. Other studies reported decreased body weight gains and organ weight effects. A NOAEL of 5 mg Ni/kg body weight was identified in the Ambrose study. This NOAEL is supported by a short term gavage study [American Biogenics, 1986].

Nickel refinery dust and nickel subsulfide are classified in Group A: Human carcinogen based on human epidemiologic data from occupational exposure via inhalation. Nickel was not demonstrated to be carcinogenic by the oral route of exposure in several animal studies. The soluble nickel salts that may be found in drinking water have not been classified as to their carcinogenic potential. Nickel is considered to be an essential trace element for some animal species, although it has not been shown to be essential for humans. It is found as a normal constituent in the human diet, with average intakes of 100 to 500 μg/day. EPA proposed an MCLG for nickel following a Category III approach considering the lack of evidence of carcinogenicity by ingestion.

Public Comments: Comments are requested on the MCLG for nickel and the carcinogenicity potential for nickel in drinking water. Fourteen comments were received. Comments were received on the derivation of the MCLG which discussed the choice of study and toxic endpoint as the basis for the MCLG, use of uncertainty factors, assumed volume of water consumed daily, exposure from water and carcinogenic potential for ingested nickel.

One commenter stated that the dose of 5 mg/kg/day should be considered a no-observed-effect level (NOEL) instead of a no-observed-adverse-effect level (NOAEL) since no effects, adverse or otherwise, were noted. They also noted that the next highest dose (50 mg/kg/d) could arguably be called a NOAEL instead of a LOAEL since the effect of decreased body weight could be the result of decreased food consumption possibly due to taste aversion.

A few comments were received on the use of a 3-fold modifying factor in the RfD calculation. These commenters said that EPA should not use the additional factor of 3 to account for deficiencies in the data base for reproductive effects because the factor of 100 is already conservative and the available

reproductive data demonstrated a NOAEL comparable to the Ambrose study. It was suggested that EPA defer establishing an MCLG for nickel until all reviews of reproductive studies are completed, which would eliminate the need for a modifying factor of 3.

Comments were received which discussed consideration of reproductive or dermatitis studies related to nickel in drinking water as the basis for the MCLG. These studies suggest that reproductive or dermatological endpoints may be more sensitive than the Ambrose feeding study. The commenters agreed with EPA's position that the reproductive and dermatitis studies were not appropriate to serve as the sole basis for the RfD due to problems with the study design. The commenters stated further that EPA has been more than conservative in using the NOAEL from the Ambrose feeding study, that there may be a potential for differential absorption from food versus water, and that the reproductive and dermatological studies in fact support the current RfD estimated from the Ambrose feeding study. Another commenter indicated that ingested nickel exerts its toxicity through irritation to the gastrointestinal tract and not inherent toxicity due to low intestinal absorption.

One commenter indicated that the DWEL should not be adjusted by a relative source contribution from water in that the DWEL is already conservative and that actual exposure data should be used. Because actual data show less exposure than EPA's default relative source contribution, the MCLG should be 5 to 6 times higher than it is. They further stated that the volume of 2 liters of water per day was an overestimate and that a value of 1.4 liters/day taken from the recommendations of the EPA Exposure Assessment Group should be used.

Several commenters supported EPA's position not to treat nickel as a carcinogen in drinking water.

EPA Response: EPA maintains that the 5 mg/kg/day dose level in the Ambrose feeding study is appropriately considered a NOAEL and that the higher dose of 50 mg/kg/day is a LOAEL. In females given the dose of 50 mg/kg/day, decreased body weight, increased relative heart weight and decreased relative liver weight were all statistically significant. Therefore, based on scientific judgment and statistical significance (concurred in by SAB), 50 mg/kg/day is considered the LOAEL. All of the above effects were also observed at the lower dose level of 5 mg/kg/day but were not statistically

significant. Thus, the 5 mg/kg/day level is a NOAEL.

EPA agrees that nickel may be irritating to the gastrointestinal tract; however, there is evidence to indicate systemic effects following chronic low dose exposure. Therefore, EPA disagrees that nickel lacks inherent toxicity.

EPA disagrees that the modifying factor of 3 is not justified. While the existing reproductive studies are not adequate for use as the sole basis for the RfD and DWEL, they do indicate a potential reproductive hazard that may result from oral exposure to nickel. A modifying factor of 3 accounts for the uncertainties for the equivocal nature of the dose-response data from the existing reproductive studies.

EPA agrees with the comments that the dermatological studies should not be the basis for the NOAEL in that oral nickel challenge studies ideally should be conducted in a double blind manner. The commentators and EPA agree, however, that the dermatological and reproductive studies support the RfD and DWEL in a weight-of-evidence approach.

The Agency disagrees with the commenter who stated that the DWEL should not be adjusted by a relative source contribution but that actual exposure data showing lower exposure should be used. EPA agrees that available data indicate that drinking water contributes less than 20 percent of the daily intake, but EPA uses 20 percent as a minimum percentage in these cases (see "Relative Source Contribution" section above).

In response to the commenter's suggestion to use 1.4 liters/day as the assumed water consumption instead of 2 liters/day, EPA continues to believe that the use of 2 liters/day is appropriate in setting the MCLGs, as recommended by NAS (1977). The Agency has consistently used 2 liters/day as an assumed consumption in past drinking water regulations. The NAS estimate was based on a survey of nine different literature sources which gave an overall average per capita water (liquid) consumption per day of 1.63 liters. It also concluded that the volume of 2 liters/day represented the intake of the majority of water consumers. In order to be conservative and allow for an adequate margin of safety, EPA uses the 2 l/day value. Further, the use of 1.4 l/day in the EPA Exposure Assessment Group handbook is not inconsistent with EPA's approach of using 2 l/day in this and other drinking water rules. The 1.4 l value is an overall average of a number of studies, some of which did not

necessarily consider indirect water consumption (such as use in cooking). Therefore, to best account for all exposures related to the occurrence of contaminants in drinking water, EPA believes use of 2 liters daily water intake is conservative and appropriate. The Exposure Assessment Group Handbook also notes that 2 liters intake is a reasonable worst case estimate.

With respect to a factor to account for potential differences in absorption of nickel from food and water, EPA acknowledges that data are available which suggest a potential for differential absorption. However, these differences are not clearly reflected in the dose-response relationships from the toxicity studies. In particular, the gavage study [American Biogenics, 1986] exposed rats to nickel chloride dissolved in water. This study identified the same NOAEL (5 mg Ni/kg/day) as the dietary study [Ambrose et al., 1976] which serves as the basis for the RfD. Thus, application of a modifying factor to account for differential absorption is not considered to be justified by the existing data.

After review of the public comments, EPA is promulgating the MCLG for nickel at 0.1 mg/l, as proposed.

e. *Sulfate.* In the July 25, 1990 notice, EPA proposed two alternative MCLGs of 400 and 500 mg/l for sulfate. People who continually ingest high levels of sulfate in their drinking water generally acclimate to the sulfate and are resistant to its laxative properties. Even though promulgation of the MCLG is being deferred, for reasons discussed in Section III.B.5 of this notice, a discussion of comments received and EPA's response follows below.

Public Comments: There were 15 separate comments concerning sulfate. Several commenters believed that EPA should not regulate sulfate due to a lack of adequate health data, lack of chronic effects and because of acclimatization (refractoriness to the laxative effects) to sulfate. Eleven commenters stated that the sulfate regulation should be higher than 500 mg/l (between 600 and 1,000 mg/l). Six commenters stated that 500 mg/l was protective, while three others believed that the 400 mg/l option would be better. One commenter stated that the usual approach for deriving the MCLG—an RfD and DWEL calculation—should be used for sulfate. Another commenter cited a 1989 letter dated July 17, 1989 from the Metals Subcommittee of the Science Advisory Board's Environmental Health Committee to the Administrator stating that the Subcommittee could not support the setting of an acute DWEL. Other commenters urged no regulation of sulfate, stating that a secondary MCL is

sufficient for sulfate, infants as well as adults acclimate to sulfate, sulfate is present in food, and the WHO guidelines are based on taste and not on health effects.

EPA Response: As noted above, EPA is deferring action on the sulfate MCLG and MCL. Some commenters noted that no chronic health effects have been associated with long-term exposure to high levels of sulfate. However, sulfate can have acute adverse effects on non-acclimated persons. The critical health effect that results from exposure to sulfate in drinking water is diarrhea. Diarrhea has been reported at a level as low as 630 mg/l. The population most likely to experience this effect consists of travelers and infants not accustomed to high sulfate levels. This laxative effect eases and disappears (i.e., the person acclimatizes to the effects of sulfate) with continued exposure to high levels of sulfate in water. Little or no information is available on how quickly people, particularly infants, acclimate to the effects of sulfate.

Due to the acute nature of the critical effect, an RfD and chronic DWEL were not determined. Available data indicate that infants may be the most sensitive subpopulation since they may be at risk of becoming dehydrated (which may be serious if not properly treated) as a result of prolonged diarrhea [Chien et al., 1968].

The Metals Subcommittee of the Science Advisory Board's Environmental Health Committee recommended additional study before regulation but noted that, if regulated, an MCLG of 400 mg/l [Loehr, 1989] was more appropriate than the 200 mg/l recommended at the time by the Agency. The basis for the SAB recommendation was that (1) the mode of action of sulfate is fairly well known, and (2) some human data are available which indicate that ill effects occur only at concentrations above 600 mg/l.

At the time EPA proposes a decision on sulfate, it will present a discussion of its science assessment, including any new information which may become available.

f. *Thallium.* EPA proposed an MCLG of 0.0005 mg/l for thallium in the July 1990 proposal [55 FR 30383]. The MCLG was derived using a NOAEL of 0.2 mg thallium/kg/day from a 13-week dietary study in rats [Stoltz et al., 1986]. Based on this NOAEL, a DWEL of 0.0023 mg/l was calculated. An uncertainty factor of 1,000 was applied (in accordance with NAS/EPA guidelines for a subchronic study). An additional uncertainty factor of 3 was used to account for the lack of adequate reproductive data. EPA has classified thallium in Group D since

there is inadequate evidence of carcinogenicity. No new data that would change the conclusions presented in the July 1990 notice have become available since its publication.

Public Comments: In response to the July 1990 notice, three individuals or organizations commented on the proposed MCLG for thallium. The most significant area of comment was the claim that the uncertainty factor of 3,000 used to establish the MCLG for thallium is overly conservative given the nature of the health effects data involved, and that an uncertainty factor of 1,000 should be sufficient. The commenter did not believe that an extra uncertainty factor of 3 was warranted for protection from potential reproductive effects.

EPA Response: EPA disagrees that the uncertainty factor of 3,000 is overly conservative. The only data available are from subchronic exposure of rodents. A factor of 1,000 is generally used with a NOAEL derived from an animal study of less-than-lifetime duration (the 1986 Stoltz et al. study was 13 weeks in length). The additional uncertainty factor of 3 was applied in the risk assessment to compensate for the lack of adequate reproductive data. In light of the results from Formigli et al. (1986) in which thallium induced testicular toxicity in rats at 0.74 mg thallium/kg/day administered in the drinking water for 8 weeks, EPA believes it is appropriate to use an additional uncertainty factor of 3 since the possibility that this effect may occur at doses at or below the selected NOAEL of 0.2 mg thallium/kg/day cannot be ruled out. Detailed descriptions of thallium toxicity at different dose levels and in different animal species are documented in the thallium Health Criteria Document prepared in support of this regulation [USEPA, 1990g, finalized in USEPA, 1992c]. Accordingly, based on the available information, the Agency is promulgating today an MCLG of 0.0005 mg/l for thallium.

4. Organic MCLGs

a. *Benzo(a)Pyrene and other PAHs.* In the July 1990 notice, EPA discussed the available information on the health effects, occurrence and human exposure for 15 Polynuclear Aromatic Hydrocarbons (PAHs) [55 FR 30396]. Of the 15 PAHs, seven were presented in greater detail because of their carcinogenic potential (all classified as Group B2, probable human carcinogen), and were proposed for regulatory consideration. These included: Benz[a]anthracene (BaA), benzo[a]pyrene (BaP),

benzo[b]fluoranthene (BbF), benzo[k]fluoranthene (BkF), chrysene (CHY), dibenz[a,h]anthracene (DBA), and indeno[1,2,3-c,d]pyrene (IPy). In the proposal, EPA presented alternative approaches for controlling exposures: (1) Setting MCLG of zero for BaP alone, based on its carcinogenic potential, and (2) setting an MCLG of zero for each of the seven carcinogenic PAHs. Only for BaP are sufficient data available to make a quantitative estimate of cancer potency. In a study wherein mice were fed BaP in the diet, treatment-related gastric tumors developed, another dietary study in rats produced similar results. Data from these studies form the basis for the quantitative estimate of cancer potency [Neal and Rigdon, 1967]. BaP is mutagenic in *vitro* mutagenicity tests, and has been found to produce reproductive effects in animals. Skin painting studies in animals indicate that the effectiveness of inducing skin cancer of the other six PAHs are equal to or less than that of BaP [see studies cited in Criteria Document [USEPA, 1988c, finalized as USEPA, 1991f]]. The Federal Register notice solicited public comments on: The Agency's two alternative options; regulation of other PAHs; and alternative approaches for evaluating the carcinogenic potency for BaP. The major comments are discussed below.

Public Comments: There were 17 comments submitted to the Agency concerning health-based issues on the proposal to regulate PAHs. Eight of the comments stated that the Agency should limit the regulation to BaP only. Three of the comments suggested regulating all seven of the Group B2 PAHs using a comparative potency approach, with comparison to BaP. One comment indicated that individual MCLGs should be established after the comparative potencies are validated. The validation method was not specified. There were several comments which suggested that the Agency should not regulate PAHs. The basis claimed for this recommendation was either that data to determine health effects were not sufficient, or that exposure to PAHs in drinking water was negligible when compared to other sources. There also were comments that did not agree with the Agency's approach of selecting Category I and setting a zero MCLG for contaminants that show evidence of carcinogenicity via ingestion. Some commenters described the Agency's approach as being overly conservative; overestimating risk; and not accounting for a threshold of carcinogenicity. Specific suggestions were: (1) To set MCLGs/MCLs at a *de minimus* level

(e.g., 10^{-4}) or at background levels; (2) use a biologically based (e.g., two-stage or fitted multistage) model to estimate cancer risk, instead of the linearized multistage model; and (3) use body weight scaling, instead of surface area, to extrapolate animal data to human exposures for estimating cancer risk.

EPA Response: EPA has decided to establish an MCLG (and MCL) for BaP only. There are extensive and sufficient data to support regulating BaP. It has been shown to be carcinogenic in animals by many routes, including by ingestion, and has been classified by the Agency as a Group B2, probable human carcinogen. Even though less than one percent of PAH exposure may come from drinking water, PAHs have been found in some drinking water sources.

The Group B2 classifications and frequency of association of the other six PAHs with BaP as a mixture in drinking water suggest that it may be appropriate to regulate these others also. The Agency is considering regulating BaA, BbF, BkF, CHY, DBA, and IPy using a comparative cancer potency approach; the individual potencies would be compared to that of BaP. Such regulation may be proposed at a future date when EPA has established a policy for how such a comparative approach would be conducted, or when other appropriate data become available for any or all of the six PAHs.

The EPA approach to estimating cancer risk for drinking water contaminants (i.e., weight-of-evidence determination and non-threshold low-dose extrapolation) is considered to be the most prudent approach that is protective of human health. The Agency considers and evaluates alternative methods for assessing human health risks to chemicals. Risk estimates using a variety of models (including two-stage, linearized multistage, and Weibull methods) have been applied to the BaP data. In the interest of using more of the available data, the slope factor of 5.76 $(mg/kg/day)^{-1}$ was derived. This slope factor is the geometric mean of all the models used. While data on the potential mechanism of action of an agent are considered in the weight-of-evidence judgment, evidence of a nongenotoxic mechanism, while pertinent, would not always exclude classification of a chemical as a probable human carcinogen. The appropriate scaling factors for interspecies extrapolation are being reviewed currently by the EPA and other Federal agencies. However, the Agency will continue to use surface area scaling to estimate cancer risks until there is sufficient evidence to support a

change and until another approach is fully approved and adopted.

Based on the above discussion, which considers the toxicity, carcinogenicity, occurrence, and exposure of BaP, BaA, BbF, BkF, CHY, DBA, and IPy, EPA has concluded that only BaP should be regulated at this time. In most cases, the Agency places Group B2 contaminants into EPA Category I when there is strong evidence of carcinogenicity via ingestion. EPA's policy is to set MCLGs for Category I chemicals at zero. Based on the weight-of-evidence for carcinogenicity, the Agency places BaP in Category I and is promulgating today an MCLG of zero for this contaminant.

b. *Dalapon.* In the July, 1990 proposal [55 FR 30385], EPA proposed an MCLG of 0.2 mg/l for dalapon based on a two-year feeding study in rats [Paynter et al., 1960]. A NOAEL of 8 mg/kg/day was identified from this study. From the NOAEL, a DWEL of 0.93 mg/l was derived. An uncertainty factor of 100 was applied to the NOAEL following NAS/EPA guidelines for a lifetime study. An additional uncertainty factor of 3 was used to account for possible inadequacy of the available animal data.

Public Comments: Three comments were received on the health effects of dalapon that were editorial in nature. There was no major disagreement between any of the commenters and EPA. One commenter misread the uncertainty factor of 300 as 800. The second commenter agreed on the value but suggested the use of the term "uncertainty factor" be used consistently to account for inadequacy of toxicological data instead of the term "modifying factor." The third commenter needed clarification on the title of a reference.

EPA Response: EPA agrees with the commenter that suggested that "3" is an uncertainty factor (which is synonymous with "modifying factor") to account for the inadequacy of the data base. Because none of the comments affect the proposed MCLG, based on the available information, the Agency is promulgating today an MCLG of 0.2 mg/l for dalapon.

c. *Dichloromethane (Methylene chloride).* In the July 1990 notice [55 FR 30386], EPA proposed an MCLG of zero for dichloromethane. This MCLG was based on the classification of this contaminant as a Group B2 carcinogen. EPA requested comments on whether the available carcinogenicity data by ingestion are adequate to classify dichloromethane in Group B2, and on the proposed MCLG.

Public Comments: Eleven comments were received in response to the

proposed regulation of dichloromethane. The majority of the commenters questioned the classification of dichloromethane in Group B2—probable human carcinogen. One commenter suggested that EPA should not regulate dichloromethane as a known human carcinogen since no human data are available. Several commenters argued for the classification in Group C while others favored a classification in Group D. These commenters stated that there are limited or inadequate data to classify dichloromethane as a Group B2 carcinogen. One commenter agreed with the EPA cancer classification in Group B2 for dichloromethane.

EPA Response: EPA disagrees with the comment that the Agency is regulating dichloromethane (DCM) as a known human carcinogen (i.e., Group A carcinogen). The Agency has classified dichloromethane in the cancer classification of Group B2, probable human carcinogen. EPA has placed dichloromethane in Category I to set the MCLG because there is sufficient evidence of carcinogenicity in animals from drinking water exposure.

EPA disagrees with the commenters supporting classification of dichloromethane in Group C (possible human carcinogen) or Group D (inadequate evidence for classification). EPA believes that there is sufficient evidence that dichloromethane induces tumors in animals. In drinking water studies [Serota et al., 1986a,b], a statistically significant increase in the incidence of combined hepatocellular carcinoma and neoplastic nodules when compared with matched controls was observed (female rats). Male mice had an increased incidence of combined neoplastic modules and hepatocellular carcinoma. In an inhalation experiment [IRIS, 1991a], statistically increased incidences of mammary adenomas and fibroadenomas were observed in male and female rats. Mice also showed increased incidence of hepatocellular adenomas and carcinomas. These data support the classification of dichloromethane in Group B2 and

provide specific evidence for ingestion exposure hazard.

Consequently, based on the information available to the Agency and the public comments received, EPA has concluded that dichloromethane should be placed in Category I, and that an MCLG of zero, as proposed, is appropriate.

d. *Di(2-ethylhexyl) adipate.* In the July 1990 proposal [55 FR 30384], EPA proposed an MCLG of 0.5 mg/l for di(2-ethylhexyl) adipate (DEHA). This MCLG was derived from an NTP 2-year dietary study in rats and mice which resulted in a NOAEL of 700 mg/kg/day [NTP, 1982a]. An uncertainty factor of 100, and an extra uncertainty factor of 10 for lack of adequate reproductive effects data, were applied to the NOAEL to derive a DWEL of 25 mg/l. The MCLG of 0.5 mg/l was calculated for DEHA from this DWEL, by applying an additional safety factor of 10 in accordance with OW policy for Group C carcinogens, and by assuming a 20 percent contribution from drinking water to total exposure.

Based on new health information (see discussion below), EPA has recalculated the proposed MCLG for DEHA. A full discussion on the basis for the revised MCLG for DEHA was given in the November 19, 1991 Notice of Availability [56 FR 60953].

Public Comments: Two commenters responded to the July 1990 proposal. Both commenters questioned the use of an extra uncertainty factor of 10 in the calculation of the DWEL to account for the lack of data on reproductive effects. One commenter claimed that the extra uncertainty factor of 10 should not be used because there are the 1988 ICI teratology and reproductive studies available for this chemical [ICI, 1988a,b].

One commenter on the NOA asserted that the 3-fold additional uncertainty factor should not be justified in part by the observation of dilated ureters in fetuses in the ICI study [ICI, 1988a], because the noted effect was not statistically significant. If these data were used to justify use of an uncertainty factor, a value less than 3

should be used, according to the commenter.

EPA Response: As discussed in the November 29, 1991 Notice of Availability, EPA has reviewed the 1988 ICI teratology and reproductive studies and considers them adequate, and suitable to serve as the basis for the MCLG for DEHA.

In the teratogenicity study, Wistar-derived pregnant rats (24/group) were fed diets containing DEHA to 0, 300, 1,800 or 12,000 ppm corresponding to dosages of 0, 28, 170 or 1,080 mg/kg/day on gestational days 1–22 [ICI, 1988a]. At the high dose, slight reductions in maternal body weight gain and food consumption were observed, and reduced ossification and kinked or dilated ureters were found in the fetuses. Slightly dilated ureters were also seen in a few fetuses at 170 mg/kg/day but the incidence did not reach statistical significance. The LOAEL and the NOAEL for this study were 1,080 mg/kg/day, and 170 mg/kg/day, respectively.

In a companion one-generation reproductive study [ICI, 1988b], groups of Wistar-derived rats (15 males/dose; 30 females/dose) were administered DEHA in their diets at the same levels (0, 28, 170 or 1,080 mg/kg/day). After 10 weeks on the diet, the animals were mated to produce one generation of offspring that was reared to day 36 post partum. Test diets were fed continuously throughout the study (approximately 18–19 weeks of exposure). No effects were seen on male or female fertility. However, at the highest dosage level, there was a reduction in the body weight gain of the dams during gestation; an increase in liver weight in both male and female parents; and reductions in offspring weight gain, total litter weight and litter size. The NOAEL for this study was also 170 mg/kg/day.

Based on the NOAEL of 170 mg/kg/day, an RfD of 0.6 mg/kg/day and a DWEL of 20 mg/l is calculated for a 70-kg adult consuming 2 liters of water per day using an overall uncertainty factor of 300.

$$RfD = \frac{170 \ mg/kg/day}{3 \times 100} = 0.56 \ mg/kg/day$$
$$(rounded \ to \ 0.6 \ mg/kg/day)$$

$$DWEL = \frac{0.6 \ mg/kg/day \times 70 \ kg}{2 \ l/day} = 21 \ mg/l$$

where:

70 kg is the assumed body weight of an adult person

100 is the uncertainty factor following EPA guidelines for a NOAEL obtained in a study using laboratory animals

3 is the additional uncertainty factor used because of data base deficiencies including lack of a multi-generation reproductive study.

In the November 29, 1991 Federal Register Notice, EPA presented this recalculated DWEL and the proposed MCLG for DEHA based on the DWEL of 21 mg/1, an additional safety factor of 10 in accordance with EPA policy for Category II contaminants, and an assumed drinking water contribution of 20% to total exposure.

$$MCLG = \frac{21 \ mg/1}{10} \times 0.2 = 0.4 \ mg/1$$

EPA agrees that because the effect on fetal ureters in the ICI study [ICI, 1988a] was not statistically significant, this effect should not be used in justifying the additional 3-fold uncertainty factor. However, EPA believes the data gap cited (lack of a multi-generation study) does warrant use of the additional 3-fold uncertainty factor.

Therefore, based on the new toxicity data, EPA is placing DEHA in Category II (Group C) and promulgating an MCLG of 0.4 mg/1 in today's notice. This MCLG of 0.4 mg/1 corresponds to a theoretical cancer risk level of 1.3×10^5.

e. *Di(2-ethylhexyl)phthalate.* In the July 1990 notice [55 FR 30398], EPA discussed the available information on the health effects, occurrence and human exposure for four phthalates: di(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diethylphthalate (DEP). In that notice, EPA proposed to set an MCLG of zero for DEHP based on its classification as a Group B2 carcinogen. The Agency based on the cancer classification on a weight-of-evidence approach for sufficient evidence of carcinogenicity in animals. DEHP caused hepatocellular adenomas and carcinomas in both sexes of rats and mice fed DEHP in the diet. The Agency discussed three regulatory options which included: regulating only DEHP based on its carcinogenicity; regulating DEHP and BBP, the latter based on a systemic toxic endpoint; and regulating all four phthalates separately, based on systemic endpoints for all except DEHP. Based on toxicity, occurrence, and exposure considerations, the Agency proposed that only DEHP should be regulated. The available occurrence data indicate that DEHP has been found most often in

drinking water while the three other phthalates have rarely been found, and the reported levels of the others are below levels of health concern. Also, drinking water is a minor route of exposure to phthalates in general, further adding to the likelihood of low risk. The Federal Register notice solicited public comments on the Agency's proposal to regulate only DEHP and also on the other options. The major comments are discussed below.

Public Comments: There were five comments submitted to the Agency concerning health-based issues on the proposal to regulate DEHP and other options. There were no comments addressing the third option, i.e., regulating all four phthalates separately. One commenter agreed with the EPA proposal to regulate DEHP only. Another commenter suggested that the MCLG for DEHP should be based on the DWEL rather than on its carcinogenicity because the evidence for carcinogenicity is insufficient. In support of this position, the commenter stated that: (1) DEHP's classification as a Group B2 carcinogen has been considered but never finalized by the Agency; (2) based on scientific uncertainty (e.g., with mechanism of action, structure activity relationships, potency, genotoxicity, species differences, etc.) a B2 classification is inappropriate; and, (3) the European community has concluded that DEHP is not a human carcinogen.

The other three comments were about BBP. The comments on BBP were: (1) That the MCL should be set only for DEHP until sufficient data exists to set MCLs for BBP and other phthalates; (2) that the classification of BBP in Group C (possible human carcinogen) is not sufficient to warrant its regulation; and (3) that the NOAEL to calculate the DWEL and MCL is quantitatively incorrect and should be increased by a factor of 3 because no dose/response relationship was found.

EPA Response: EPA does not agree with the position that there is a lack of evidence for classifying DEHP as a probable human carcinogen. According to the Agency's Guidelines for Carcinogen Risk Assessment [USEPA, 1986], the overall weight-of-evidence provides sufficient evidence in animals to classify DEHP as a Group B2 (probable human) carcinogen. EPA's CRAVE verified the Group B2 classification for DEHP on November 7, 1987. The classification was based upon the NTP study [NTP, 1982b], which resulted in a statistically significant increased incidence of hepatocellular carcinomas and adenomas in female rats and both sexes of mice. Additionally, there was a statistically

significant increase in the combined incidence of neoplastic nodules and hepatocellular carcinomas in high dose male rats. The 13 factors presented in the comment, to support the view that DEHP does not have an appreciable cancer risk, do not conclusively support an absence of cancer risk to humans (see comment response document for detailed discussion). The EPA approach, i.e., weight-of-evidence consideration and non-threshold low-dose extrapolation, is considered protective of human health and EPA has concluded that the weight of evidence for DEHP warrants classification in Group B2, according to the EPA Guidelines for Carcinogen Risk Assessment. In most cases, the Agency places Group B2 contaminants into EPA Category I and sets MCLGs at zero when there is strong evidence of carcinogenicity from drinking water. EPA's policy is to set MCLGs for Category I chemicals at zero. The fact that the European communities have concluded that DEHP is not a human carcinogen is noted, but it does not necessitate that EPA adopt such a position, especially in the context of setting drinking water regulations according to the strict standard in the SDWA ("no known or anticipated" human health effects with an "adequate margin of safety"). After reviewing the public comments, EPA has concluded that an MCLG of zero, as proposed, based on the available evidence of carcinogenicity in animals, is appropriate for DEHP.

With regard to the comments on BBP, EPA believes that to set an MCL for BBP alone would incorrectly suggest (as discussed above) that the available data are not adequate to regulate DEHP as a carcinogen. A DWEL for BBP was determined based upon systemic toxic effects to the liver, kidney, and testes. When selecting a NOAEL, EPA does not necessarily rely upon the conclusions published with the study. The NOAEL for BBP was based upon liver weight change and the value selected was corroborated by evidence from other studies. The rationale for selecting the NOAEL can be reviewed in the health criteria document for phthalates [USEPA, 1991g]. An additional uncertainty factor for limited cancer evidence was incorporated to develop the proposed MCLG for BBP; however, the Agency is not finalizing the MCLG at this time.

Considering the toxicity, occurrence, and exposure of DEHP and BBP, EPA has decided to regulate DEHP only because it appears more likely to occur in drinking water and is more toxic. Based on the weight-of-evidence on

carcinogenicity, the Agency is promulgating today an MCLG of zero for DEHP, as proposed.

f. *Dinoseb*. In the July 1990 proposal [55 FR 30387], EPA proposed an MCLG of 0.007 mg/l for dinoseb based on a two-year study in rats [Hazleton, 1977]. A LOAEL of 1 mg/kg/day was identified from this study. An uncertainty factor of 1,000 (as per NAS/EPA guidelines for a LOAEL) was used in the derivation of the DWEL of 0.035 mg/l. This LOAEL of 1 mg/kg/day was also supported by a 100-week mouse study [Brown, 1981] and a 3-generation reproductive study in rats [Irvine, 1981]. The proposed MCLG was based upon this DWEL and an assumed drinking water contribution of 20 percent of the total intake. Dinoseb was placed in Category III (Group D) based on the lack of evidence of carcinogenicity.

Public Comments: One comment was received on the health effects of dinoseb. The commenter agreed with EPA that dinoseb should be placed in Group D (inadequate evidence of carcinogenicity). However, this commenter questioned the rationale for using 1,000 instead of 100 as the uncertainty factor in the calculation of the DWEL.

EPA Response: The Agency used an uncertainty factor of 1,000 in the calculation of the DWEL in accordance with the NAS/EPA guidelines for use of a LOAEL, in the absence of a NOAEL, from an animal study. Therefore, based on the available toxicological data for dinoseb, EPA is promulgating today an MCLG of 0.007 mg/l for dinoseb, as proposed.

g. *Diquat*. EPA proposed an MCLG of 0.02 mg/l for diquat in the July 1990 proposal [55 FR 30389] following a Category III approach. The MCLG of 0.02 mg/l was derived from a chronic feeding study in rats [Colley et al., 1985] A NOAEL of 0.22 mg/kg/day was identified from this study. A DWEL of 0.08 mg/l was calculated by applying an uncertainty factor of 100. The MCLG of 0.02 mg/l assumes a drinking water contribution of 20 percent of the total intake. EPA has placed this contaminant in Category III based on the lack of information on its carcinogenicity. No new data that would change the conclusions presented in this notice have become available since its publication.

Public Comments: EPA received one comment on the proposed MCLG for diquat. The commenter indicated that an online computer search of the Hazardous Substances Data Base (HSDB) showed that diquat causes nausea, vomiting, diarrhea, possible liver and kidney damage, dyspnea, and

pulmonary edema. The commenter also noted that diquat appears to affect epithelial tissues primarily and may attack those of the kidney or lens of the eye preferentially.

EPA Response: EPA agrees with the commenter that diquat causes the above mentioned effects when used at high doses in animal tests. These effects were discussed in the Health Criteria Document for diquat prepared in support of the July 1990 proposal [USEPA, 1990e; finalized as USEPA, 1992g]. However, the effects reported in the Federal Register notice are effects associated with the critical endpoint of toxicity used to establish the no-observed-adverse-effect level (NOAEL) for diquat. The effects described by the commenter are acute effects noted only at much higher dose levels than the dose causing the critical effects described in the notice. Therefore, based on the available health information, the Agency is promulgating today an MCLG of 0.02 mg/l for diquat, as proposed.

h. *Endothall:* EPA proposed an MCLG of 0.1 mg/l for endothall in the July 1990 proposal [55 FR 30390]. The MCLG was derived from a 24-month feeding study in beagle dogs [Keller, 1965]. This study identifies a NOAEL of 2 mg/kg/day. A DWEL of 0.7 mg/l was derived for the 70-kg adult by applying an uncertainty factor of 100 (in accordance with NAS/EPA guidelines). The MCLG for endothall was then calculated at 0.1 mg/l by applying a 20 percent contribution from drinking water. EPA has placed this contaminant in Category III (Group D) based on the lack of adequate data on its carcinogenic potential. No new data that change the conclusions presented in this notice have become available since its publication.

Public Comments: EPA received one comment on the proposed MCLG for endothall. This commenter indicated that there is a one-year dog study [Greenough et al., 1987] with a higher NOAEL of 6 mg/kg/day that the commenter believes would be more suitable for the calculation of the reference dose than the 2 mg/kg/day NOAEL from the two-year dog study by Keller (1965) used by the Agency. He further indicated that the effects noted by the Agency in the Keller study (increased organ weight and organ-to-body weight ratios) are not, in his opinion, "clearcut adverse effects" because no effects on body weight gain or food consumption were seen at any dose level.

EPA Response: The Agency agrees with this commenter that the additional one-year dog study on endothall [Greenough et al., 1987; MRID #407452-02], which was not available at the time

the MCLG was proposed, should be considered. The data from this study are summarized below.

In a 12-month dietary study in dogs, disodium endothall was fed to groups of four male and four female beagle dogs at levels of 0, 150, 450, or 1,350 ppm [Greenough et al., 1987]. After 6 weeks of dosing, the dietary level at the highest dose was reduced to 1,000 ppm because of anorexia, decreased food consumption and body weight loss. Compound intake in the low-, mid- and high-dose groups was approximately 6, 18 and 35.8 mg/kg/day endothall disodium. After the highest dose had been reduced to 1,000 ppm, a partial recovery of the weight loss was observed, but the overall weight gain remained lower than in controls. No effects on weight gain were observed at 150 or 450 ppm. However, based on the histologic changes in the liver and reactive hyperplastic response in the gastric mucosa, the LOAEL is 450 ppm (14.4 mg/kg/day endothall ion), and considering the marginal effects on the stomach at the lowest level, the NOAEL is probably slightly lower than 6 mg/kg/day endothall disodium (equivalent to 4.8 mg/kg/day endothall ion).

The Agency notes that the lowest dose tested in the Greenough et al. dog study of 4.8 mg/kg/day endothall ion (150 ppm) provides supportive evidence that the noted low grade epithelial irritation may contribute to more remarkable effects when the animals are exposed to endothall for a longer period of time as noted in the two-year dog feeding study by Keller (1965). Although no effects were observed on body weight gains or on food consumption in the two-year dog feeding study [Greenough et al., 1987], the increased weights and organ-to-body weight ratios for the stomach and intestine in this study were dose-dependent and must be considered in the risk assessment of this chemical, considering that it is an irritant.

The dog appears to be more sensitive to adverse effects from endothall than the other animal species tested (as discussed in the proposal). EPA has concluded that the Keller (1965) study is the most appropriate study based on the effects noted above. Accordingly, the Agency is promulgating today an MCLG of 0.1 mg/l for endothall, as proposed.

i. *Glyphosate*. EPA proposed an MCLG of 0.7 mg/l for glyphosate in the July 1990 proposal [55 FR 30392]. The MCLG of 0.7 mg/l was derived from a three-generation rat study [Biodynamics, 1981a]. This study showed a statistically significant increase in kidney lesions. The NOAEL was identified at 10 mg/kg/

day. A DWEL of 3.5 mg/1 was derived by applying an uncertainty factor of 100, which is in accordance with NAS/EPA guidelines. The MCLG of 0.7 mg/1 for glyphosate was calculated by applying a 20 percent contribution from drinking water.

Several additional toxicity studies on glyphosate submitted to the Agency since publication of the July 1990 notice have been evaluated. However, these studies do not provide new information that would change the MCLG proposed in that notice. The proposal noted that EPA has classified glyphosate as a Category III (Group D) chemical. In today's notice, the Agency still places glyphosate in Category III (Group D) for establishing the MCLG.

Public Comments: In response to the July 1990 notice, two individuals or organizations commented on the MCLG proposal for glyphosate. One commenter noted that over-exposure to glyphosate may result in mucous membrane irritation, abdominal pain, vomiting, hypertension, oliguria, and anuria. The other commenter claimed that the July 1990 notice did not document adequately the results of some of the toxicological studies with glyphosate and did not include the most recent data on this chemical, such as a new two-generation rat reproduction study [Reyna, 1990], which concerned much higher doses than the 1981 three-generation rat study by Biodynamics that was used in establishing the proposed MCLG. This commenter also claimed that the oral LD_{50} in mice is 10 g/kg and that information on the toxicokinetics of glyphosate is not "very limited" as stated in the July 1990 notice. The commenter requested that the discussion of the chronic rat study of 1981b by Biodynamics be revised as follows:

Because of the absence of a dose-dependent effect, the lack of preneoplastic changes, the wide variability in the spontaneous incidence of this tumor, the similarity in incidence between the high dose group and historical controls, the lack of any evidence of genotoxicity, it was concluded that the observed incidence *did not demonstrate an oncogenic response* (emphasis added).

and that the statement on the three generation rat study of 1981a by Biodynamics also be corrected to:

In the three-generation rat reproduction study and addendum, the most significant finding was focal, unilateral, renal tubular dilation in the kidneys of male pups for the F_{3b} generation of high-dose dams (30 mg/kg/day). The NOEL for this effect was 10 mg/kg/day. No effects on fertility or *reproductive* parameters were noted" (emphasis added).

EPA Response: In response to the first commenter, the Agency notes that acute effects are already discussed in the Health Criteria Document for glyphosate [USEPA, 1990f]. The preamble to the proposal generally discussed only effects noted at the lowest effect level and not the acute toxicity effects that may occur at much higher dose levels.

In response to the second commenter, the Agency agrees to include the revised language quoted above in the Public Comment Response Document [USEPA, 1992a] with respect to both the three-generation rat reproduction study [Biodynamics, 1981a] and the chronic rat study [Biodynamics, 1981b]. The Agency believes that this revised language is appropriate. It does not change the bases for the MCLG. The criteria document [USEPA, 1992b] discusses these issues in detail.

On reconsideration, the Agency agrees with this commenter that the data on the toxicokinetics of glyphosate is not "very limited". The available information as documented in the updated Health Criteria Document for glyphosate (1991) indicate the 97.5 percent of the absorbed dose by rats is eliminated in urine and feces. The alpha half-lives ranged from 2.11 to 7.52 hours for males and 5 to 6.44 hours in females while the beta half-lives ranged from 69 to 181 hours and 80 to 337 hours for males and females, respectively.

In response to the commenter's statement that the LD_{50} in mice is 10 g/kg, a lower LD_{50} in mice of 1.6 g/kg was reported by Bababunmi et al. (1978), as noted in the proposal.

The Agency also notes that a new lifetime rat feeding study [Stout and Ruecker, 1990, MRID #416438–01, volumes 1–6] was recently submitted to the Agency and is being reviewed. As per the commenter's recommendation to use the new two-generation rat study [Reyna, M.S., 1990, MRID #416215–01], for the MCLG calculations, this study was submitted to the Agency only recently and is fully described in the updated Health Criteria Document [USEPA, 1992b] prepared in support of today's rule. This new study is still under evaluation by the Agency. It is unlikely that this study will be considered an appropriate basis for the NOAEL and MCLG because the NOAEL in this study is 500 mg/kg/day, whereas adverse effects were noted at a much lower dose level (30 mg/kg/day) in the three-generation reproduction study in rats [Biodynamics, 1981a].

Therefore, EPA has concluded that the three-generation study in rats [Biodynamics, 1981a] is appropriate for the derivation of the MCLG for glyphosate, and is promulgating today

an MCLG of 0.7 mg/l for this contaminant, as proposed.

j. *Hexachlorocyclopentadiene (HEX).* EPA proposed an MCLG of 0.05 mg/l for hexachlorocyclopentadiene in the July 1990 proposal [55 FR 30394]. The MCLG of 0.05 mg/l was derived from a 13-week oral toxicity study in rats [SRI, 1981]. The only effect reported was slight depression of body weight. A NOAEL of 10 mg/kg/day was identified from this study. A DWEL of 0.25 mg/l was calculated by applying an uncertainty factor of 1,000, which is appropriate for use with a NOAEL derived from animal study data that are significantly less-than-lifetime in duration. The MCLG of 0.05 mg/l was calculated from the DWEL of 0.025 mg/l by applying 20 percent contribution from drinking water. No new data that would change the conclusions presented in this notice have become available since its publication.

Public Comments: EPA received one comment on the proposed MCLG for hexachlorocyclopentadiene in the July 1990 notice. The commenter indicated that the toxicity data in the SRI study are inadequate to justify setting an MCLG and suggested that EPA postpone regulation of hexachlorocyclopentadiene until adequate toxicity studies are available.

EPA Response: Although EPA realizes that the toxicity data base is not as extensive as for some contaminants, EPA believes that there are sufficient toxicity data to regulate hexachlorocyclopentadiene. The SRI data were reviewed by the Agency's Reference Dose (RfD) Workgroup, which verified the Reference Dose using these data. In addition, EPA is required by the 1986 amendments to the SDWA to regulate hexachlorocyclopentadiene. Therefore, based on the available data, the Agency is promulgating today an MCLG of 0.05 mg/l for hexachlorocyclopentadiene, as proposed.

k. *Simazine.* EPA proposed an MCLG of 0.001 mg/1 for simazine in the July 1990 proposal [55 FR 30402]. The MCLG was derived from a DWEL of 0.058 mg/l (rounded to 0.06 mg/l), applying a 20 percent contribution from drinking water and an additional 10-fold safety factor by considering the classification of simazine in Category II (limited evidence of carcinogenicity from drinking water). The MCLG was based upon a NOAEL of 0.5 mg/kg/day for non-carcinogenic effects in a 2-year rat chronic feeding/oncogenic study [McCormick et al., 1988, MRID #406144–03] and was supported by a NOAEL of 0.7 mg/kg/day in a 1-year dog feeding

study [McCormick and Green, 1988, MRID #406144–02].

Several uncertainty factors were applied to this NOAEL: 10-fold to account for interspecies extrapolation and another 10-fold to account for intraspecies variability, plus an additional 3-fold factor to account for the absence of an adequate study (data gap) to assess the potential toxic effects of simazine on reproduction. The proposal also indicated that if the data gap for reproduction is filled before finalizing the simazine MCLG and if the data from this study would not raise any specific toxicological concerns at the dose used in the calculation of the MCLG, 0.5 mg/kg/day, the 3-fold uncertainty factor may be dropped and the DWEL would then be 0.2 mg/1 and the MCLG would be 0.004 mg/l [55 FR 30404, footnote]. This MCLG lies in the range of 10^{-5} cancer risk estimates.

As noted in the November 29, 1991 Notice of Availability, subsequent to the July 1990 proposal, the data gap concerning reproduction effects has been filled. The Agency recently received a two-generation rat reproduction study [Epstein, 1991, MRID #418036–01] where simazine was tested at 10, 100 and 500 ppm (these doses are equivalent to 0.5, 5 and 25 mg/kg/day using Lehman (1959) conversion from ppm to mg/kg/day) assuming rats consume 5 percent of their body weight daily. No effects were noted in this reproduction study at the dose level (0.5 mg/kg/day) used to calculate the MCLG. In light of these data, EPA indicated in the Notice of Availability of November 29. 1991 that it was considering dropping the 3-fold uncertainty factor from the calculation of the DWEL and the MCLG for simazine as EPA had indicated it would do in the proposal [55 FR 30404, Footnote]. EPA has now decided in today's final rule to drop the 3-fold uncertainty factor. Accordingly, the proposed DWEL and MCLG of 0.06 and 0.001 mg/l, respectively, are modified and finalized (after rounding) at 0.2 and 0.004 mg/l, respectively.

Public Comments: Two individuals or organizations commented on the MCLG for simazine. One commenter questioned the reliability of the current animal studies for simazine if the Agency has to use an additional 3-fold uncertainty factor in the calculation of the DWEL. This commenter was also concerned that the chemical may have been placed in Group C (possible human carcinogen) based on the similarity between simazine and atrazine or propazine. He claims that the justification for the cancer classification of simazine being placed in Group C

should be made solely on the basis of animal data.

The second commenter agreed that EPA should use the non-carcinogenic data for establishing the MCLG for Group C chemicals. This commenter added that Group C contaminants are not suitable for the quantitative cancer risk assessment process.

Several comments on the NOA were received which discussed this issue. All of the commenters on the NOA supported use of the Epstein study [Epstein et al., 1991] and dropping the additional 3-fold uncertainty factor.

EPA Response: In response to the first commenter, EPA believes that the animal studies used in the calculation of the DWEL for simazine are adequate studies and provide reliable information to calculate the DWEL. The additional 3-fold uncertainty factor was originally applied to account for the absence of an adequate reproduction study. As discussed above, the 3-fold uncertainty factor is not being used in the final DWEL or MCLG calculation in today's notice.

As to this commenter's concern that simazine should be placed in Group C based only on animal data and not on the similarity with atrazine or propazine, the Agency notes that simazine has been placed in Category II based on the weight-of-evidence approach and not only because of the structure-activity relationship with atrazine and propazine. Simazine has been found to cause mammary gland tumors in Sprague-Dawley rats. This effect was also noted with other analogues: atrazine, propazine, and recently with cyanazine. This fact adds to the weight-of-evidence of the carcinogenicity of simazine in this animal species and supports EPA's classification of simazine in Group C.

In response to the second commenter's contention that all Group C contaminants are unsuitable for quantitative cancer risk assessment, the Agency disagrees. In some cases, adequate dose-response data from a single study may be available, even though the weight of evidence is inadequate for a Group B classification.

In the July 1990 proposal the Agency described two options for the calculation of the MCLG for Category II (i.e., Group C) contaminants such as simazine, one using the RfD approach, with an additional safety factor, and another using the cancer quantification approach.

Many drinking water contaminants placed in Category II have been classified as Group C, possible human carcinogen, due to the limited nature of

the weight of evidence for carcinogenicity. For Group C, the existing cancer risk assessment guidelines [USEPA, 1986] allow some flexibility as to whether to quantify the risk. Quantification should be carried out on a case-by-case basis, depending on various factors, including the adequacy of the data.

For Group C contaminants, the MCLG is usually based on the RfD approach when sufficient non-carcinogenic data are available. An additional 1- to 10-fold safety factor is used to account for the possible carcinogenicity. The resulting MCLG can then be compared to the cancer risk if the data are quantifiable. If adequate data are not available to determine an RfD, then the MCLG is set at the 10^{-5} to 10^{-6} excess cancer risk level where such quantification is appropriate.

EPA under FIFRA examines the risk for Group C contaminants like simazine using both an RfD approach and quantification of cancer risk using the cancer potency. Either method may be an appropriate method for risk management decisions.

As noted in the July 1990 proposal, carcinogenic potency for simazine at 1.2 $\times 10^{-1}$ mg/kg/day^{-1} was determined from the incidence of mammary gland tumors in female Sprague-Dawley rats [McCormick et al., 1988; MRID #406144–05]. Based on this carcinogenic potency, simazine concentrations of 0.003 and 0.0003 mg/l were associated with theoretical cancer risk levels of 10^{-5} and 10^{-6}, respectively.

The Agency also has sufficient non-carcinogenic data to determine an RfD. Using the RfD and a 10-fold safety factor, EPA calculated an MCLG of 0.004 mg/l. This MCLG corresponds to a theoretical cancer risk level of 1×10^{-5}. The 10-fold safety factor used by EPA to calculate this MCLG is justified based on the possible cancer risk associated with this chemical as expressed in the rat chronic/oncogenic study [McCormick et al., 1988; MRID #406144–05]. This study was used for both the calculation of the cancer potency based on mammary gland tumors and the derivation of the RfD based on a NOAEL of 0.5 mg/kg/day for other systemic toxicity, like the noted reduction in the female body weight gain and the significant changes in the hematology parameters. This RfD is also supported with the NOAEL of 0.7 mg/kg/day from a one-year dietary exposure study in the dog [McCormick and Green, 1988; MRID #406144–02].

Using the RfD approach with an additional safety factor, the Agency is promulgating today an MCLG of 0.004

mg/l for simazine assuming a daily consumption of 2 liters of water by a 70 kilogram adult and applying a 20 percent relative source contribution from drinking water. This MCLG of 0.004 mg/l corresponds to the theoretical cancer risk level of 1×10^{-5}.

l. *1,2,4-Trichlorobenzene.* EPA proposed an MCLG of 0.009 mg/l for 1,2,4-trichlorobenzene (TCB) in the July 1990 proposal [55 FR 30405]. The MCLG of 0.009 mg/l was derived from a subchronic inhalation study in rats [Watanabe et al., 1978]. A NOAEL of 1.31 mg/kg/day and a DWEL of 0.046 mg/l were identified, resulting in an MCLG of 0.009 mg/l when applying a 20 percent contribution from drinking water.

Public Comments: In response to the July 1990 notice, three individuals or organizations commented on the MCLG proposed for 1,2,4-trichlorobenzene. Each commenter criticized EPA's use of an inhalation study to derive a health assessment value and regulatory standard for drinking water ingestion.

EPA Response: In response to the public comments received for the July 1990 proposal, EPA has reexamined the database for trichlorobenzene. The Agency agrees with the public comments stating that in the case of 1,2,4-trichlorobenzene the oral RfD should not be based upon the Watanabe inhalation study [Watanabe et al., 1978]. Upon reexamination of the oral studies, EPA determined that the Robinson et al. (1981) study provides the best scientific basis for determination of an RfD for 1,2,4-trichlorobenzene, as discussed in the November 1991 Notice of Availability [56 FR 60953]. This study was a multi-generation reproductive study in rats that were dosed with 0, 25, 100 and 400 ppm 1,2,4-trichlorobenzene added to the drinking water for 95 days per generation for two generations and examination of the offspring of the F_1 rats. The only compound-related changes seen in the dams or offspring were significant increases in adrenal gland weights of the P_0 and F_1 generations.

To more specifically characterize the changes noted in this study, an in-house EPA study was performed. It was found that the increased adrenal weights were associated with the histopathologic lesion, vacuolization of the zona fasciculata of the cortex. The Robinson study determined a NOAEL at the 100 ppm dose (14.8 mg/kg/day). Based on this study and applying an uncertainty factor of 1,000 to account for sensitive human subpopulations, extrapolation from an animal study, and for use of a study which was less than lifetime, the RfD is 0.01 mg/kg/day and the DWEL is

0.35 mg/l (verified by the RfD/RfC Workgroup [USEPA, 1991b]). Applying a relative source contribution of 20 percent, EPA is today promulgating an MCLG of 0.07 mg/l based upon the Robinson study, as proposed in the Notice of Availability.

EPA received two comments on the NOA, both of which supported EPA's use of the Robinson study [Robinson et al., 1981] as the basis for the 1,2,4-trichlorobenzene RfD and MCLG.

m. *1,1,2-Trichloroethane.* EPA proposed an MCLG of 0.003 mg/l for 1,1,2-trichloroethane in the July 1990 proposal [55 FR 30406]. The MCLG of 0.003 mg/l was derived from two 90-day drinking water studies in mice [Sanders et al., 1985; White et al., 1985]. A NOAEL value of 3.9 mg/kg/day was used to calculate a DWEL of 0.14 mg/l, by applying an uncertainty factor of 1,000 (per NAS/EPA guidelines for a NOAEL derived from a less-than-lifetime study). The proposed MCLG of 0.003 mg/l was calculated from the DWEL by applying an additional safety factor of 10 because of the classification of 1,1,2-trichloroethane in Group C (limited evidence of carcinogenicity as evidenced by the presence of hepatocellular carcinomas and adrenal pheochromocytomas in mice but not rats) and by applying 20 percent contribution from drinking water.

Public Comments: In response to the July 1990 notice, two individuals commented that the use of an uncertainty factor of 1,000 indicated that reliable data do not exist for the development of a DWEL. Another commenter was confused about the use of an extra 10-fold safety factor for a chemical classified as a Group C chemical and asked for clarification about the use of an extra safety factor and the rationale for its use.

EPA Response: In response to the comments about the use of a 1,000 uncertainty factor, EPA prefers to use data from lifetime studies to set DWELs and MCLGs. However, EPA often regulates chemicals that do not have a complete data base; for example, there may be no lifetime studies in animal species. In such cases, an additional 10-fold uncertainty factor is applied to account for the "data gap," per NAS/EPA guidelines.

As described previously in today's notice, EPA has developed a three-category approach for setting MCLGs for chemicals in drinking water. For chemicals in Category II (compounds having limited evidence of carcinogenicity via drinking water), the MCLG is usually based on the use of the RfD approach with an additional safety factor of 1 to 10 to account for possible

carcinogenicity. If the data are not sufficient to calculate an RfD, then the MCLG is set in the 10^{-5} to 10^{-6} lifetime cancer risk range. Since the Agency has verified an RfD for 1,1,2-trichloroethane (verification date 8/01/90) [IRIS, 1991h], EPA has used the RfD approach with an additional safety factor of 10 (to account for possible carcinogenic effects) to derive the MCLG for 1,1,2-trichloroethane. Based on this approach and after consideration of public comment, EPA is promulgating today an MCLG of 0.003 mg/l for 1,1,2-trichloroethane, as proposed. This MCLG of 0.003 mg/l corresponds to the theoretical cancer risk of 10^{-5}.

n. *2,3,7,8-Tetrachlorodibenzo-p-dioxin.* EPA proposed an MCLG of zero for 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD; dioxin) in the July 1990 proposal (55 FR 30384). This proposal MCLG was based on the classification of 2,3,7,8-TCDD in Group B2; probable human carcinogen. New data [i.e., Fingerhut et al., 1991 and other studies] have become available to EPA since the publication of the July 1990 notice. Critical reviews of much of these data, including reassessments of critical cancer studies and new epidemiology studies are under way but have not been completed by the Agency to date. The Agency is undertaking a complete reassessment of the risks from dioxin which includes a review of the entire health effects data set for 2,3,7,8-TCDD as well as additional laboratory studies. The Agency expects to complete its reassessment including a full peer review by 1993.

Until that time, the Agency believes it is appropriate to proceed to regulate 2,3,7,8-TCDD in drinking water using the existing health data and the current peer-reviewed risk assessment. Consequently, the Agency is regulating 2,3,7,8-TCDD based on the risk assessment presented in the July 1990 proposal. Once EPA has completed its critical review of the new health information, the Agency will initiate a process to determine whether the MCLG for 2,3,7,8-TCD should be revised.

Public Comments: In response to the notice of July 1990, 12 individuals or organizations commented on the MCLG proposal for 2,3,7,8-TCDD. Several commenters believed EPA's proposed MCLG was too stringent and several believed the MCLG was appropriate, but that the MCL was too lenient.

Four commenters believe that the cancer potency of 2,3,7,8-TCDD has been overstated by the Agency and cited the re-review of the Kociba cancer slides by the EPA Pathology Working Group (PATHCO) as evidence [Kociba

et al., 1978]. The PATHCO's panel of experts found two-thirds fewer tumors than the original Kociba study, and concluded that those found were correlated with toxicity, suggesting a threshold mechanism. These commenters also indicated that the PATHCO findings have already been recognized by EPA as scientifically defensible since the Agency approved the Maryland Water Quality Standard, which relied on these findings.

One commenter stated that there is a large body of epidemiological evidence on 2,3,7,8-TCDD which has found no association between dioxin and human cancer, and that the Agency is therefore not justified in basing all its mathematical extrapolations on cancer data from rat studies. This commenter also stated that the linear multistage model used to qualify cancer risk for 2,3,7,8-TCDD was the incorrect model since the reexamination of the Kociba et al. (1978) data indicates no linear dose response and evidence of a threshold cancer response.

The same commenter urged EPA to revise the cancer potency factor based on the most recent reexamination of the Kociba et al. (1978) data done by the PATHCO.

Two commenters criticized the fact that the MCLG/MCL applies only to 2,3,7,8-TCDD, even though the Agency acknowledges that other isomers of polychlorinarted dibenzo-p-dioxin (PCDD) and polychlorinated dibenzofurans (PCDF) have similar toxic properties as estimated by the 2,3,7,8-TCDD toxic equivalency factor (TEF) methodology. The commenter claims that the MCLG/MCL should be based on the TEF approach.

One commenter believes that EPA's proposal of a zero MCLG for 2,3,7,8-TCDD is inappropriate since data indicate that the chemical promotes cancer through a receptor mediated mechanism, thus indicating it is a threshold carcinogen. The commenter indicated that 2,3,7,8-TCDD is not a tumor initiator but is more likely a tumor promoter.

One commenter stated that the average dioxin exposure among the general population exceeds EPA's calculated reference dose (RfD) and that it is unacceptable for EPA to allow any further dioxin exposure. The commenter also stated that the Agency failed to consider more recent data showing adverse reproductive effects for 2,3,7,8-TCDD at doses lower than those cited in the July 1990 proposal. The commenter claims that an up-to-date RfD would be 10 times more stringent than the RfD cited in the July 1990 proposal.

EPA Response: EPA disagrees with the commenters who stated that the MCLG for 2,3,7,8-TCDD is too stringent. The Agency has placed this compound in Category I and is setting the MCLG at zero based on its carcinogenic potential.

EPA disagrees with the commenters who alleged that EPA has already approved the Kociba et al. (1978) re-reed as part of its approval of the Maryland water quality standard for 2,3,7,8-TCDD. Maryland did not incorporate a re-read of the Kociba study in developing their water quality standard for 2,3,7,8-TCDD. Instead, Maryland used the FDA cancer potency estimate for this contaminant.

In response to the concerns raised about the cancer potency, EPA is presently reviewing the cancer potency of 2,3,7,8-TCDD as part of its complete reassessment of dioxin. The Agency is also investigating the mechanism of carcinogenicity, including assessing the likelihood of a potential threshold mechanism and appropriateness of the current extrapolation model. However, at this time, the Agency has not completed its risk assessment or subjected it to peer review and therefore has made no decisions to change its assessment of the cancer potency or the possible threshold mechanism for dioxin. As stated above, the Agency expects to complete its reassessment in 1993. Given this time frame and the legal mandate to regulate 2,3,7,8-TCDD in drinking water, the Agency has relied on the data available at the time of the July 1990 proposal.

EPA does not agree with the commenter who stated that there is a large body of epidemiology data on 2,3,7,8-TCDD which has found no association between dioxin and human cancer. EPA stated in the July 1990 proposal that taken together, the epidemiology studies based on exposure to 2,3,7,8-TCDD by themselves are inadequate to establish a relationship between 2,3,7,8,-TCDD and the development of tumors in humans. More recent data, however (including Fingerhut 1991 and studies from Germany and Italy), are being evaluated together with the previous epidemiology studies as part of the overall reassessment of dioxin, and EPA expects to reach its conclusions within the timeframe noted above.

EPA is considering revising the cancer potency based on the re-read of the Kociba et al. (1978) data and other data such as body weight/surface area corrections. In addition, EPA will assess the entire data base, including the issue of threshold carcinogenicity, and possible immunotoxicity and reproductive toxicity at low levels, before embarking on a change in the

cancer risk characterization. Because dioxin is currently considered a B2 carcinogen by the Agency, the MCLG is being set at zero.

EPA agrees that new data published since development of the proposed criteria document might support a different RfD. As part of an overall reassessment of dioxin toxicity, EPA is reviewing studies on immunotoxicity and reproductive effects in addition to the cancer data. The RfD and DWEL would become relevant to setting the MCLG for dioxin only if it were determined that this compound is in fact a threshold carcinogen with a potency so low that other non-cancer effects become the most sensitive endpoints of toxicity. This point will be considered in the re-evaluation of the risk assessment of 2,3,7,8-TCDD.

In response to the commenter who stated that EPA should regulate all isomers of polychlorinated dibenzo-p-dioxin (PCDD) and polychlorinated dibenzofurans (PCDF) using the toxic equivalency factors (TEF) approach, EPA is not considering the regulation of other related compounds at this time. The Agency has no indication that these compounds are found in public water supplies. The Agency is regulating 2,3,7,8-TCDD in today's rule because it is the most potent isomer and it is included in the list of 83 contaminants to be regulated under the SDWA.

In response to the claim that EPA should not propose an MCLG of zero for 2,3,7,8-TCDD because it is a threshold carcinogen, the Agency's reassessment, again, is reviewing all the health effects data on 2,3,7,8-TCDD in an effort to update the cancer risk characterization of 2,3,7,8-TCDD. However, until the Agency has completed its reassessment, the Agency will continue to consider 2,3,7,8-TCDD to be a non-threshold contaminant and, thus, maintain an MCLG of zero for 2,3,7,8-TCDD. Because the analytic limitation for drinking water compliance monitoring for dioxin is at 30 ppq, a significant change in the risk assessment, and consequently the MCLG, would be needed before an increase in the final MCL would result.

Detailed descriptions of 2,3,7,8-TCDD toxicity at different dose levels and in different animal species are documented in the 2,3,7,8-TCDD Health Criteria Document prepared in support of this regulation [USEPA, 1988d]. This document is available in the Drinking Water Public Docket.

Based on the available information, EPA is promulgating today an MCLG of zero for 2,3,7,8-TCDD.

o. Endrin, hexachlorobenzene, oxamyl, picloram. For four

contaminants, no significant issues were raised and no new health effects information was obtained by the Agency that would cause it to change the MCLGs from the level proposed in July 1990. Therefore, for these contaminants (endrin, hexachlorobenzene, oxamyl and picloram), final MCLGs are promulgated in today's notice as proposed, as presented in Table 2.

B. Establishment of MCLs

1. Methodology for Determination of MCLs

The SDWA directs EPA to set the MCL "as close to" the MCLG "as is feasible." The term "feasible" means "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 costs into consideration)." (SDWA section 1412(b)(5)). Each National Primary Drinking Water Regulation that establishes an MCL lists the technology, treatment techniques, and other means which the Administrator finds to be feasible for meeting the MCL (SDWA section 1412(b)(6)).

The present statutory standard for "best available technology" (BAT) under 1412(b)(5) 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 to the SDWA changed BTGA to BAT and added the requirement that 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 its performance has been validated in a reliable manner. In addition, EPA believes that the technology selected need not necessarily have been field tested for each specific contaminant but, rather, that the operating conditions may be projected for a specific contaminant using a field tested technology from laboratory or pilot systems data.

Based on the statutory directive for setting the MCLs, EPA derives the MCLs based on an evaluation of (1) the availability and performance of various technologies for removing the contaminant, and (2) the costs of applying those technologies. Other technology factors that are considered in determining the MCL include the ability of laboratories to measure accurately and consistently the level of the contaminant with available analytical methods. For Category I contaminants, the Agency also evaluates the health risks that are associated with various levels of contaminants, with the goal of ensuring that the maximum risk at the MCL falls within the 10^{-4} to 10^{-6} risk range that the Agency considers protective of public health, therefore achieving the overall purpose of the SDWA.

EPA's initial step in deriving the MCL is to make an engineering assessment of technologies that are capable of removing a contaminant from drinking water. This assessment determines which of those technologies are "best." EPA reviews the available data to determine technologies that have the highest removal efficiencies, are compatible with other water treatment processes, and are not limited to a particular geographic region.

Based on the removal capabilities of the various technologies, EPA calculates the level of each contaminant that is achievable by their application to large systems with relative clean raw water sources. [See H.R. Rep. 1185, 93rd Cong., 2nd Sess. at 13 (1974); 132 Cong. Rec. S6287, May 21, 1986, statement of Sen. Durenberger.]

When considering costs to control the contaminants in this rule, EPA analyzed whether the technology is reasonably affordable by regional and large metropolitan public water systems [See H.R. Rep. No. 93–1185 at 18 (1974) and 132 Cong. Rec. S6287 (May 21, 1986) (statement of Sen. Durenberger)]. EPA also evaluated the total national compliance costs for each contaminant considering the number of systems that will have to install treatment in order to comply with the MCL. The resulting total national costs vary depending upon the concentration level chosen as the MCL. The more stringent the MCL, the greater the number of systems that may have to install BAT in order to achieve compliance and the higher the national cost. In today's rule, EPA has determined that costs for large systems and total national compliance costs at the final MCLs are reasonable, affordable and, therefore, feasible.

One commenter urged EPA to apply cost-effectiveness analysis in selecting the MCLs for the contaminants in this rule. EPA did consider the relative cost-effectiveness of regulatory alternatives in selecting the proposed MCLs for radionuclides in a recent notice (July 18, 1991 [56 FR 33050]). In the radionuclides proposal, EPA collectively analyzed the regulated contaminants based on the fact that all cause cancer by delivering ionizing radiation to body tissue. Ionizing radiation is itself classified as a group A carcinogen. Comparing the relative cost effectiveness of controlling different sources of ionizing radiation dose formed the basis for choosing the most cost-effective alternative for proposal in the radionuclides rule. While EPA sought public comment on broader use of cost-effectiveness analysis, the Agency did not suggest that it would be applying a similar analysis to all other drinking water regulations, and EPA does not believe that cost-effectiveness analysis should be applied to the MCL selections in today's rule since the factors that made this analysis appropriate in the radionuclide proposal radionuclides notice are not present here.

The feasibility of setting the MCL at a precise level is also influenced by laboratory ability to measure the contaminant reliably. EPA derives practical quantitation levels (PQLs) which reflect the level that can be measured by good laboratories under normal operating conditions with specified limits of precision and accuracy. Because compliance with the MCL is determined by analysis with approved analytical techniques, the ability to analyze consistently and accurately for a contaminant at the MCL is important to enforce a regulatory standard. Thus, the feasibility of meeting a particular level is affected by the ability of analytical methods to determine with sufficient precision and accuracy whether such a level is actually being achieved. This factor is critically important in determining the MCL for contaminants for which EPA sets the MCLG at zero, a number of which by definition can be neither measured nor attained. Limits of analytical detection require that MCL be set at some level greater than the MCLG for these contaminants. In these cases, EPA examined the treatment capability of BAT and the accuracy of analytical techniques as reflected in the PQL to establish the appropriate MCL level.

EPA also evaluates the health risks that are associated with various contaminant levels in order to ensure that the MCL adequately protects the

public health. For drinking water contaminants, EPA sets a maximum reference risk range of 10^{-4} to 10^{-6} excess individual risk from a carcinogen over a lifetime. This policy is consistent with other EPA regulatory programs that generally target this range using conservative models that are not likely to underestimate the risk. Since the underlying goal of the Safe Drinking Water Act is to protect the public from adverse effects due to drinking water contaminants, EPA seeks to ensure that the health risks associated with MCLs for carcinogenic contaminants are not significant.

Below is a discussion of how today's MCLs were determined, including the Agency's response to comments on the proposed rule.

2. Inorganic Analytical Methods

In the July 1990 notice, the Agency proposed a list of analytical methods for measuring the five inorganic chemicals (IOCs) in today's rule. These analytical methods are considered to be economically and technologically feasible for compliance monitoring. In the November 29, 1991 notice of availability (NOA), new information received by the Agency on these methods was made available for public comment. The NOA included new and updated versions for analytical methods, performance data on the proposed methods and corrections to some of the information included in the proposal related to the method detection limits. The NOA also addressed several issues that were raised during the public comment period for the July 1990 proposal. EPA has analyzed the available information and has considered the public comments on the proposal and the NOA in arriving at the final selection of the inorganic methods and their associated MDLs and PQLs.

The analytical methods being promulgated today are in some respects revised from those proposed, as indicated in the NOA, and as discussed below. These methods were selected based on the following factors: (1) Reliability (i.e., precision/accuracy) of the analytical results; (2) specificity in the presence of interferences; (3) availability of enough equipment and trained personnel to implement a national monitoring program (i.e., laboratory availability); (4) rapidity of analysis to permit routine use; and (5) cost of analysis to water supply systems.

Table 11 lists the analytical methods that EPA is approving today for use to comply with the monitoring requirements in this rule. EPA has updated the references to the most recent editions of the relevant manuals, including the atomic absorption, emission, and mass spectrometric methods for metals, the spectrometric and electrode methods for cyanide. These newer editions are generally very similar, and in some cases identical, to the methods proposed in the July 1990 notice.

TABLE 11.—APPROVED METHODOLOGY FOR INORGANIC CONTAMINANTS AND METHOD DETECTION LIMITS (MDLS)

Contaminant	Method	MDL (mg/l)
Antimony	Atomic absorption, Furnace	0.003
	Atomic Absorption, Platform	[4] 0.0008
	ICP-Mass Spectrometry	0.0004
	Hydride-Atomic Absorption	0.001
Beryllium	Atomic Absorption, Furnace	0.0002
	Atomic Absorption, Platform	[4] 0.00002
	Inductively Coupled Plasma [1]	0.0003
	ICP-Mass Spectrometry	0.0003
Nickel	Atomic Absorption, Furnace	0.001
	Atomic Absorption, Platform	[4] 0.0006
	Inductively Coupled Plasma [1]	0.005
	ICP-Mass Spectrometry	0.0005
Thallium	Atomic Absorption, Furnace	0.001
	Atomic Absorption, Platform	[4] 0.0007
	ICP-Mass Spectrometry	0.0003
Cyanide	Distillation, Spectrophotometric [2]	0.02
	Distillation, Automated, Spectrophotometric [2]	0.005
	Selective Electrode [2]	0.05
	Distillation, Amenable, Spectrophotometric [3]	0.02

[1] Using a 2X preconcentration step as noted in Method 200.7. Lower MDLs may be achieved when using a 4X preconcentration.
[2] Screening method for total cyanides.
[3] Measures "free" cyanides.
[4] Lower MDLs are reported using stabilized temperature graphite furnace atomic absorption.

The reliability of analytical methods used for compliance monitoring is critical at the MCL. Therefore, EPA evaluates the analytical methods with respect to accuracy and recovery (lack of bias) and precision (good reproducibility) at the MCL level.

When NPDWRs are revised or new regulations are proposed, the Agency examines available methods and only those methods which meet all the necessary criteria are proposed. Public comments on the applicability of these methods are taken into consideration when the rule is finalized.

a. Metals (antimony, beryllium, nickel and thallium). Atomic Absorption Methods—Several parties commented on whether it was appropriate to use the four-times concentration procedure, described in Appendix to Method 200.7, for furnace techniques. They questioned whether EPA should allow the use of this concentration procedure in conjunction with the furnace techniques for the analyses of antimony and thallium. After reconsideration, EPA agrees with these commenters that adequate data to support the use of this procedure in conjunction with the furnace technique for the analysis of antimony and thallium are not available. EPA has, therefore, revised the table of approved methods by eliminating the use of the concentration step for the analysis of antimony and thallium. However, this concentration step is being approved for use in conjunction with Method 200.7 for the analysis of nickel and beryllium.

The corresponding method detection limits (Table 11) for these techniques, as well as others as discussed in the NOA, have been corrected to reflect the MDLs listed in the referenced analytical methods. There were several commenters who were supportive of

these corrections. However, they had concerns on how the resulting corrections would be used in the setting of the PQLs. This issue is addressed below in the PQL discussion.

ICP–Mass Spectrometric Method (EPA Method 200.8)—Several commenters had concerns with the listing of EPA Method 200.8 as an approved method because of the following: (1) the absence of an interlaboratory method validation study, (2) the limited availability in laboratories, and (3) the high acquisition cost of the instrumentation. With respect to the first point, the Agency recognizes the usefulness of interlaboratory performance data and has recently completed an interlaboratory method validation study (Determination of Trace Elements in Water by Inductively Coupled Plasma-Mass Spectrometry: Collaborative Study by J.E. Longbottom et al., 1991), which was made available for public comment with the NOA. The resulting study data indicate that laboratories using the ICP–MS method are quite capable of meeting the performance criteria (i.e., MDL, PQL and acceptance limits) designated for the metal contaminants in this rule. EPA received no public comments on these data.

With respect to the second point regarding the limited availability of laboratories, the Agency believes that laboratory capability will expand with time. Although ICP–MS is not currently widely used, EPA expects a progressive evolution of the technique and an increase in its use analogous to the development and use of another mass spectrometry technique, gas chromatography/mass spectrometry (GC/MS). When GC/MS was first introduced, it was considered state-or-the-art and few labs had the expertise or instrumentation to employ the technique. However, its use expanded quite rapidly and today there are very few laboratories that do not have the GC/MS instrumentation and employ this technique for routine analyses. The change in availability of GC/MS is attributed mostly to advantages and benefits for multi-analyte techniques, as discussed below. EPA believes this trend will also occur with the ICP–MS technique. Furthermore, this technique is only one of many being approved for use in the analyses of the metals in today's rule. Laboratories with the ICP–MS capability may use it for analysis of the metals in this rule, and those labs without it may use another method or consider acquiring ICP–MS instrumentation.

In response to the third point regarding high acquisition costs of

instrumentation, EPA believes that while ICP–MS represents a substantial capital investment for labs, there are a number of cost advantages associated with having ICP–MS capability, i.e., sensitivity, multiple metals analysis capability and high volume sample throughput. ICP–MS is a stable and precise technique capable of excellent accuracy and very low detection limits, thus providing a laboratory with the option of performing multielement analysis using one technique. Another cost advantage can be realized when comparing the cost of running each individual metal analysis on an atomic absorption spectrophotometer versus the cost of simultaneous multiple metals analyses on ICP–MS. Despite the high initial capital cost, ICP–MS capability is cost-effective because of the speed of analysis it provides, thus reducing operational costs. EPA believes that these advantages will allow laboratories using ICP–MS to expand their capabilities and expertise and increase their productivity.

In conclusion, EPA has determined that ICP–MS is both technically and economically feasible for routine compliance monitoring and is designating it as one of the approved analytical methods for conducting monitoring for the metals in today's rule.

Digestion for Metals—Commenters to the NOA expressed concerns about the clarity of EPA's requirements for the use of the "total metals" technique and for digestion of drinking water samples prior to metals analysis. The commenters noted, first, that pp. 3–5 of Section (3030) of the seventeenth edition of the Standard Methods for the Examination of Water and Wastewater [USEPA, 1983], states:

"Colorless, transparent samples (primarily drinking water) containing a turbidity of <1 NTU, no odor, and single phase may be analyzed directly by atomic absorption spectroscopy or inductively coupled plasma spectroscopy for total metals without digestion * * *."

The commenter also noted that EPA's 1933 "Method for Chemical Analysis of Water and Wastes" (MCAWW) on page Metals-5 states:

"Drinking water samples containing suspended material and settleable material should be prepared using the total recoverable procedure (4.1.4) * * *.", which includes a digestion step.

The commenters believe that, in light of these statements, samples without suspended and settleable materials may not have to be digested. The commenters stated that they recognize

that, under certain circumstances, both digested and undigested drinking water samples should be compared to verify that metals are being properly recovered.

EPA agrees that the requirements for the use of the "total metals" technique and for digestion of drinking water samples may not be clear, which could result in different interpretations by different analysts. In addition to the notes above, page Metals-1 of the "Method for Chemical Analysis of Water and Wastes" (MCAWW) states that:

"While drinking waters free of particulate matter may be analyzed directly, domestic and industrial wastes require processing to solubilize suspended material."

While digestion may be necessary for turbid water samples, EPA does not believe it is critical for non-turbid, clean drinking water samples. The current methodologies being cited for metal analyses of drinking water samples are applicable for samples of other matrices. However, EPA agrees the guidance cited above on whether to digest or not to digest drinking water samples may not be very clear. EPA believes that results from analyses using the approved total element techniques, i.e., graphite furnace AA and ICP, can be reported as "total metals" for non-turbid (<1 NTU) samples that have been properly preserved (conc HNO_3 to pH <2), because under these circumstances the "total metals" result is equal to the "dissolved metals", since the concentration of the "suspended metals" would be negligible. However, samples containing a turbidity greater than one (>1 NTU) even though properly preserved, require digestion using the total recoverable technique as defined in the approved methods, and can be reported as "total metals". Therefore, to provide clarity for the "total metals" technique and to determine whether to digest or not to digest drinking water samples, EPA is amending the current requirement as footnoted in the tables of approved methodology. The revised footnotes will state:

[6] Samples that contain less than 1 NTU (nephelometric turbidity unit) and which are properly preserved (conc HNO3 to pH <2) may be analyzed directly (without digestion) for total metals; otherwise, digestion is required. Turbidity must be measured on the preserved samples just prior to the initiation of metal analysis. When digestion is required, the total recoverable technique as defined in the method must be used.

[10] For the gaseous hydride determination of Sb and Se, or for determination of Hg by the cold vapor technique, the proper digestion technique as defined in the method must be followed to ensure the element is in the proper chemical state for analyses.

EPA believes that this revision will provide clarity for "total metals" analysis and a means for determining whether digestion is required when performing metals analyses in this rule. To provide consistency for all metals analyses for drinking water samples, EPA is also incorporating these footnotes, when applicable, by amending the tables of approved methodology in § 141.23(k)(4), which includes the metals in the January, 1991 rule, and § 141.89(a), which includes lead and copper.

b. *Anions (cyanide and sulfate).* (1). *Cyanide.* In the November 29, 1991 NOA, EPA addressed an issue raised in response to the July 1990 notice stating that although the proposed MCLG was based on "free" cyanide, the proposed analytical methods determine "total" cyanide. EPA concurred with commenters that it was appropriate to include methods that determined cyanide amenable to chlorination, or "free" cyanide. For this reason, the NOA proposed to add a methodology for amenable cyanide to the list of approved methods, and this notice finalizes the addition. The "total" cyanide methods are listed as well because they are adequate to screen samples for cyanide. If the "total" cyanide levels are greater than the MCL, then analysis for "free" cyanide should be performed to determine whether there is an MCl exceedance. The "total" cyanide analysis is still recommended as an initial test because it is cheaper than the amenable cyanide method. There are several commenters to the NOA who supported this action.

Several commenters had concerns with the approval of the titrimetric method for cyanide because of its lack of sensitivity (detection limit of 1 mg/l) with respect to the PQL, which was proposed to be set at 0.2 mg/l. EPA agrees with these commenters and has rescinded the approval of this method and deleted it from the list of approved methods. The spectrophotometric method has been added to the list of approved methods for cyanide because this method has adequate sensitivity. This change was indicated in Table 6 of the NOA. Comments received by EPA supported these revisions.

(2) *Sulfate.* A number of comments on sulfate analytic methods were received. Commenters objected to the absence of the methylthymol blue method from the list of approved methods and to the fact that the "non-suppressed" column is not stated as an acceptable option in Method 300, an ion chromatography method, for sulfate analysis [USEPA, 1989d].

EPA agrees with the commenters that the methylthymol blue method is adequate. However, there are no data to support the use of the non-suppressed column and the commenters submitted no data to support it.

Commenters to the NOA objected to the presence of the chloranilate method for sulfate analysis and stated that the chloranilate method has several problems. They stated that the required reagent (anhydrous chloranilate) is hard to find and that only a single vendor from England sells this form of the reagent. Second, the analytical equipment called for in the method is no longer available from the manufacturer. In addition, ASTM has dropped this method from its most recent edition of published methods and EMSL/CINN (EPA) is considering doing this as well. EPA agrees with the commenters on all these points.

However, as discussed above, EPA is deferring promulgation of a final regulation for sulfate, and so is not promulgating analytic methods for sulfate in today's final rule.

c. *Method detection limits and practical quantitation levels.* In the July 1990 notice, there were some inconsistencies and errors in the listed method detection limits (MDLs) of the cited methodologies for some of the inorganic contaminants. Several commenters to the proposal and the NOA expressed concerns with these errors and inconsistencies. The Agency addressed those concerns in the November 29, 1991 NOA and in this final rule, respectively, by making the appropriate corrections, as shown in the NOA, and by clarifying how the MDLs were used in setting the PQLs, as discussed below.

EPA determines practical quantitation levels (PQLs) for each substance for the purpose of integrating analytical chemistry data into regulation development. This becomes particularly important where MCLGs are zero or a very low concentration, near or below the detection limit. The PQL yields a limit on measurement and identifies specific precision and accuracy requirements which EPA uses to develop regulatory requirements. As such, PQLs are a regulatory device rather than a standard that labs must specifically demonstrate they can meet. The following is a discussion of how EPA determined the PQLs for the inorganic contaminants in today's rule.

The proposed PQLs in the July 1990 notice for cyanide and nickel were determined based upon MDLs and results from water pollution (WP) performance evaluation (PE) data as these data were available for concentrations near the MCLGs. There were no PE data available at the proposed MCLG levels for antimony, beryllium and thallium. Therefore, the proposed PQLs for these contaminants were estimated from the respective MDLs by using "five or ten times the MDL" to set the PQL. Only the proposed PQL for thallium was affected by the corrected MDLs discussed in the NOA.

Several commenters had concerns with EPA using the "five or ten times the MDL" to set the PQLs for antimony, beryllium and thallium. They asserted that it is not feasible to measure these contaminants at these PQLs. As discussed in other FR notices, EPA prefers to set PQLs based on PE data or multi-laboratory collaborative study data; however, when such data are not available, EPA uses the generalized rule of "5 to 10 times the MDL" to set the PQL. Where data becomes available, EPA evaluates the data to verify the generalization or make the appropriate change(s) dictated by the data.

EPA believes that the proposed PQLs for the inorganic contaminants are technologically and economically feasible and that in general the "5 to 10 times the MDL" rule is a good estimate of laboratory practical quantitation capability for drinking water analyses. This assertion has now been corroborated by evaluations of Water Supply (WS) performance data for the five inorganic contaminants in today's rule.

Several commenters to the NOA had concerns on how the WS performance data would be used. EPA has used the data in setting the PQLs in this rule as it has for most of the regulated inorganics, as discussed below.

The final PQLs for all five inorganics were derived from data gathered in recent Water Supply (WS) PE studies, using the procedure described in 54 FR 22100, May 22, 1989. The use of this procedure has been well documented. The final acceptance limits and PQLs for antimony, beryllium and thallium are based on EPA and State data from Water Supply PE studies #024–027 [USEPA, 1991d]. These PE studies were also evaluated to verify the earlier PE data on which EPA based the proposed acceptance limits and PQLs for cyanide and nickel. The new study data, made available for public comment in the November 29, 1991 NOA, indicated (1) for antimony and thallium, for which

two options were proposed, that their PQLs be set at 0.006 mg/1 and 0.002 mg/1, respectively (2) that the PQLs for nickel and cyanide should be lowered (the proposed PQLs for nickel and cyanide were already at levels that were at or below the proposed MCLGs) and (3) that the PQL for beryllium should remain the same as proposed.

The PQL procedure, described in the aforementioned May 22, 1989 notice, generates acceptance ranges, i.e., a range of acceptable variation in the analytical results compared to the known or "true" value. The acceptance limits for the inorganics in today's rule were generated using the procedure used to derive PQLs and the laboratory performance data generated in Water Supply Studies 24–27, which were discussed in the NOA. The PQLs were set at a concentration where it was estimated that at least 75 percent of the EPA and State labs are within the specified acceptance ranges. The final acceptance limits (1) are tighter than

proposed for cyanide, (2) are based on the data rather than two standard deviations for antimony, beryllium and thallium and (3) remained the same for nickel as proposed. The resulting PQLs and acceptance limits are shown in Table 12.

TABLE 12.—INORGANIC CONTAMINANT ACCEPTANCE LIMITS AND PRACTICAL QUANTITATION LEVELS

Inorganic contaminant	MCL (mg/1)	Acceptance limits (plus or minus % of the true value)	PQL (mg/1)
Antimony	0.006	30	0.006
Beryllium	0.004	15	0.001
Cyanide	0.2	25	0.1
Nickel	0.1	15	0.01
Thallium	0.002	30	0.002

d. *Inorganic chemical sample preservation, container, and holding times.* The requirements for sample

preservation, containers and holding times listed in Table 13 were proposed for the inorganic contaminants in this rule. One commenter on the NOA mentioned that the addition of 0.6 gram of ascorbic acid in the preservation of cyanide is not applicable to all samples, and that the specific procedure in the methods should be followed to determine the measure of ascorbic acid required. EPA agrees with the commenter and has amended the table accordingly.

No other comments were received on these requirements. Therefore, the Agency is promulgating these requirements today, as listed.

TABLE 13.—INORGANIC CONTAMINANT SAMPLE PRESERVATION, CONTAINER, AND HOLDING TIME REQUIREMENTS

Contaminant	Preservative [1]	Container [2]	Maximum holding time [3]
Antimony	Conc HNO₃ to pH <2	P or G	6 months.
Beryllium	Conc HNO₃ to pH <2	P or G	6 months.
Cyanide	Cool, 4°C, NaOH to pH >12 [4]	P or G	14 days.
Nickel	Conc HNO₃ to pH <2	P or G	6 months.
Thallium	Conc HNO₃ to pH <2	P or G	6 months.

[1] Samples that cannot be acid preserved at the time of collection because of sampling limitations or transportation restrictions should be acidified with nitric acid to a pH <2 upon receipt in the laboratory. Following acidification, the sample should be held for 16 hours before withdrawing an aliquot for sample processing and/or analysis.
[2] P = plastic, hard or soft; G = glass, hard or soft.
[3] In all cases, samples should be analyzed as soon after collection as possible.
[4] Ascorbic acid should only be used in the presence of residual chlorine.

3. Organic Analytical Methods

A minimum of eight of the 17 methods included in today's rule are needed to measure the 18 organic contaminants (Table 14). Eleven methods have been in use or promulgated in other rules; there were no significant comments on them. Four methods are single-analyte methods (i.e., they measure only one analyte). Most systems will conduct compliance monitoring for contaminants to which they are vulnerable using one of the volatile organic chemical (VOC) methods and one to three other methods—Methods 515.1, 525.1 and 531.1—all of which may be used to measure the organic contaminants regulated in two previous rules promulgated on July 8, 1987 [52 FR 25690] and January 30, 1991 [56 FR 3526].

Some commenters asked that when EPA permits flexibility in method selection by citing more than one method for a contaminant, that the detection limit, practical quantitation limit (PQL) and maximum contaminant limit (MCL) be set differently for each method; EPA disagrees. Although method detection limits (MDLs) as calculated by the procedures in 40 CFR 136, appendix B may sometimes differ for an analyte measured with different methods, for regulatory purposes EPA must set a single PQL and MCL. Since laboratories can sometimes achieve lower MDLs than those cited for a specific listed method, EPA believes that a laboratory which routinely achieves the detection limits specified for a contaminant (Table 14), should be

permitted to use that method for compliance monitoring.

EPA also received comments recommending the use of alternate analytical procedures. Because reliable compliance data are necessary for enforcement of the regulations, EPA continues to cite only methodologies included in EPA regulations, as summarized in the guidance contained in the laboratory certification manual. However, EPA recognizes that improvements in analytical technology may occur frequently. Thus, the Agency is developing a regulatory process to expedite the revision and updating of older methods and the inclusion of new methods for drinking water compliance analysis.

TABLE 14.—ANALYTICAL METHODS, DETECTION LIMITS, MDLs, PQLs, MCLs AND MCLGs FOR ORGANIC CHEMICALS [1]

EPA method No. [3]	Contaminant	MDL	PQL	MCL	MCLG [2]
502 1, 502.2, 524.1, 524.2	Dichloromethane	0.0002	0.005	0.005	zero
502.2, 503.1, 524.2	1, 2, 4-Trichlorobenzene	0.0003	0.005	0.07	0 07
502 1, 502.2, 524.1, 524.2	1, 1, 2-Trichloroethane	0.0001	0.005	0.005	0.003
1613 [2]	2, 3, 7, 8-TCDD (Dioxin)	5×10^{-9}	3×10^{-8}	3×10^{-8}	zero
525 1, 550, 550.1	Benzo (a) pyrene	0.00002	0.0002	0.0002	zero
506, 525:1	Di (2-ethylhexyl) adipate	0.0006	0.006	0.4	0 4
506, 525 1	Di (2-ethylhexyl) phthalate	0.0006	0.006	0.006	zero
505, 508, 525.1	Endrin	0.00001	0.001	0.002	0.002
505, 508, 525.1	Hexachlorobenzene	0.0001	0.001	0.001	zero
505, 525.1	Hexachlorocyclopentadiene	0.0001	0.001	0.05	0.05
505, 507, 525.1	Simazine	0.00007	0.0007	0.004	0.004
515.1	Dalapon	0.001	0.01	0.2	0.2
515.1	Dinoseb	0.0002	0.002	0.007	0.007
515 1	Picloram	0.0001	0.001	0.5	0 5
531 1	Oxamyl (Vydate)	0.002	0.02	0.2	0 2
547	Glyphosate	0.006	0.06	0.7	0.7
548	Endothall	0.009	0.09	0.1	0.1
549	Diquat	0.0004	0.004	0.02	0.02

[1] All concentrations are in mg/1.
[2] Method 1613 [USEPA, 19901].
[3] All 500 Level Methods [USEPA, 1988e and USEPA, 1990k].

a. *Method-specific comments.* Some comments were received on individual chemicals- -phthalates, adipates, 2,3,7,8-TCDD (dioxin), dalapon, dichloromethane, endothall and polynuclear aromatic hydrocarbons (PAHs)—and on certain methods being approved for drinking water regulations for the first time—Methods 506, 547, 548, 549, 550, 550.1, 513 and 1613 [USEPA, 1988e and 1990k].

Several commenters believe that not enough laboratories will be certified to timely conduct compliance monitoring analyses; EPA disagrees. These comments were similar to those raised and answered in 56 FR 3550 in the rule promulgated on January 30, 1991. EPA also received a comment on the NOA [56 FR 60949] about the effect of starting the monitoring on January 1, 1993 rather than January 1, 1996. EPA recognizes that an earlier compliance monitoring start-date accelerates the need for certification. EPA also believes there is some confusion about the criteria for obtaining laboratory certification.

EPA acknowledges that fewer laboratories currently are proficient with some of the single-analyte methods and the 2,3,7,8-TCDD Method 1613 than with older pesticide and volatile organic chemical methods. These same concerns were raised by commenters when EPA included newer methods in the rule promulgated January 30, 1991. EPA again expects systems to use vulnerability assessments as a cost affective way to characterize trends in their water quality and thereby be eligible for renewable monitoring waivers. For these and other reasons stated in the 1991 rule (56 FR 3550) EPA believes an adequate number of laboratories will have opportunity to obtain certification

or provisional certification for these contaminants in today's rule.

Some commenters were concerned that high background contamination or interferences would make reliable detection and precise measurement of adipates, phthalates and dichloromethane difficult or impossible at the detection and MCL concentrations listed in the July 1990 notice. They believe that many false positives for dichloromethane, in particular, would occur due to ambient air conditions in the laboratory or sample collection site. All EPA methods detailed careful procedures that must be followed to minimize or eliminate interferences or contamination that can occur in sample collection, shipment, storage and analysis. In EPA's laboratory performance evaluation studies more than 75 percent of the laboratories have routinely and successfully analyzed samples with dichloromethane at concentrations near the practical quantification level of 0.005 mg/1. This affirms that laboratories appear to be taking precautionary steps outlined in the methods.

Based on public comment and further testing, EPA has modified Method 506 for the analysis of adipates and phthalates. EPA switched from ternary solvent mixture to the binary methylene chloride and hexane solvent mixture, which is used in a previously promulgated EPA method, EPA Method 606. Using this modification, a very good precision of ±6 percent was obtained in replicate measurements at concentrations near the practical quantification level.

EPA acknowledges that methods can often be improved and the Agency works to refine them and to adopt new

analytic technology and techniques. For example, EPA's Environmental Monitoring Systems Laboratory in Cincinnati is working to change derivatization procedures that use diazomethane for the measurement of several chemicals, including dalapon. Dalapon is now measured with Method 515.1. EPA plans to include dalapon in the next version of Method 552, which will be named 552.1. Method 552.1 replaces diazomethane with acidic methanol in the derivatization step, and liquid-liquid extraction is replaced by liquid-solid extraction. This should reduce interferences and improve the precision of the analysis.

EPA also plans to change the procedure (Method 548) for measurement of endothall. The new method would be named Method 548.1. It would replace pentafluorophenylhydrazine with acidic methanol in the derivatization step, and liquid-solid extraction is used. The electron capture detector is replaced with a flame ionization detector in the new method. Data and method write-ups were not available in time for these methods (552.1 and 548.1) to be included in today's rulemaking. However, EPA anticipates adopting these methods for compliance monitoring of dalapon and endothall as soon as possible after they are released by the Environmental Monitoring Systems Laboratory.

An early success is EPA Method 1613, which is a consolidated method for the measurement of 2,3,7,8-TCDD (dioxin) in all matrices. It replaces Method 513, which had been cited in the July 25, 1990 proposal and as the method for monitoring dioxin as an unregulated contaminant in the rule promulgated January 30, 1991 [56 FR 3592,

§ 141.40(n)(11)]. This rule promulgates its use only for drinking water. Its use in other media will be promulgated as part of the appropriate regulations.

EPA agrees with commenters who stated that only one polynuclear aromatic hydrocarbon (PAH), benzo(a)pyrene, should be regulated at this time (see earlier discussion in Section III–4). Three analytical methods were proposed in the July 1990 notice for the measurement of benzo(a)pyrene. Method 550 and 550.1 use high pressure liquid chromatography (HPLC). Method 525 uses a gas chromatograph connected to a mass spectrometer. No significant comments were received on these methods. Methods 550 and 550.1 are included in today's rule for compliance analyses [USEPA, 1990k].

Several commenters asked for more mass spectrometer methods to increase the number of analytes in an analysis and to decrease the probability of interferences that can cause false positives. EPA proposed multi-analyte mass spectrometric Method 525 in the July 25, 1990 proposal. As discussed in an earlier Federal Register notice (56 FR 30272, July 1, 1991), EPA improved the method, renumbered and adopted it as Method 525.1. Because Method 525.1 supersedes Method 525, EPA is adopting 525.1 for seven organic chemicals in today's rule.

Method 525.1 has the potential to measure a large number of organic chemicals; the question is whether the required sensitivity can be achieved. As always, laboratories using this method (and other methods) for compliance analysis must demonstrate an ability to achieve the detection limits specified in Section 141.24 using the procedure described in 40 CFR part 136, appendix B.

Some commenters requested that EPA consolidate methods across all EPA programs and in all media. EPA realizes the difficulty laboratories may have in conducting certified analyses for the same organic chemical in several matrices over a wide range of concentrations using similar yet different EPA methods. Through EPA's Environmental Methods Management Council, EPA is working to consolidate methods, performance requirements and definitions of quantitation and detection. Regulatory, quality assurance, enforcement and other issues make this a complicated task.

b. *Responses to comments specific to Method 1613 for dioxin.* EPA has received comments related to the application of Method 1613 to the measurement of chlorinated dioxins and furans in drinking water. Some of these comments address a narrow range of

issues, primarily the Method Detection Limit (MDL) and practical quantitation limit (PQL). Others are very extensive in that nearly every aspect of the technical details in Method 1613 are addressed. In organizing its response to the comments submitted, the Agency has responded to general issues first, then to comments specific to the technical details of Method 1613.

Some comments on Method 1613 overall are incorporated into these comment replies. Many commenters were concerned about the performance of Method 1613 on sample matrices other than drinking water, particularly on treated and untreated industrial wastewaters, paper pulp, and sludge from wastewater treatment processes. EPA stated in the proposal of this rule [55 FR 30426] that Method 1613 was developed for these matrices. In 1991 EPA proposed Method 1613 for analysis of these matrices by industrial discharges under the Clean Water Act (proposed amendment to 40 CFR part 136 in 56 FR 5090, February 7, 1991), and solicited comments on that proposal. To date, EPA has not responded to the comments received on that proposal. Because EPA desires to move quickly on today's drinking water rule, EPA is responding to comments on Method 1613 related to application of the method to drinking water prior to responding to comments on the February 7, 1991 proposal of Method 1613.

General issues concerning Method 1613. A commenter noted that Method 1613 has not been promulgated. EPA agrees. As mentioned above, EPA proposed Method 1613 under section 304(h) of the FWPCA at 40 CFR part 136 on February 7, 1991, accepted comments at that time, and has not promulgated Method 1613 in part 136 as of today's date. EPA has used data from its studies of Method 1613 to support the practical quantitation limit (PQL), the Method Detection Limit (MDL), and other technical aspects of the regulation of dioxin in drinking water, in the same way that EPA references other documents in support of its rules. The Agency is not required to use promulgated methods for reference purposes.

A commenter stated that EPA Office of Water Method 1613 and Office of Solid Waste SW–846 Method 8290 are significantly different, contradicting recommendations to Congress in the report titled "Availability, Adequacy and Comparability of Testing Procedures for the Analysis of Pollutants Established Under section 304(h) of the Federal Water Pollution Control Act" [USEPA, 1988f]. The commenter provided a block diagram

showing differences in these two methods. EPA agrees that the two methods are different in exact technical detail, but the measurement principle of the two methods is the same. In developing testing methods for its regulatory programs, such methods evolve at different rates for different purposes. For example, Method 1613 was originally developed primarily for use in treated and untreated effluents, but is applicable to pulps, sludges, drinking water and other solid and semi-solid matrices. Similarly, EPA Method 8290 was developed for use primarily in solid and semi-solid matrices, but is applicable to analysis of water. EPA is in the process of consolidating methods for dioxin measurement in air, water, and solid waste, consistent with the recommendations in the report that the commenter references. However, such a merger cannot take precedence over EPA's development of methods to meet specific program needs and for regulatory programs with Congressional deadlines and court-ordered timetables.

A commenter stated that, although EPA used Method 1613A for analysis of more than 500 samples, there have been many versions of this method and the data produced using these versions were inaccurate. EPA acknowledges that some data produced with early versions of Method 1613 may have been less accurate than data produced with more recent versions. Much of these earlier data were developed using complex matrices, such as industrial effluents, and were generated as the method was being developed. The method and MDL proposed in the November 1991 notice, and being finalized here, are based not on these early data but on later data generated using reagent water, which is a matrix more similar to drinking water. The accuracy of analytic methods usually improves with experience in using the method. However, the fact that data become more accurate as a function of time does not mean that earlier data are necessarily unsuitable for their intended purpose. The Agency is careful to consider in its rulemaking the effects of the variability of the analytical data. For example, in this rulemaking, data variability is accounted for in the determination of the MDL, and is considered in setting the PQL.

A commenter noted that Method 1613 calls for instrument calibration to be verified at a high level, but that calibration should be verified instead at the minimum level, because of uncertainties at that level. EPA disagrees that calibration should be verified at the minimum level. In method

1613, calibration is verified at the mid-point of the analytical range. This verification is common and accepted practice for analytical methods (see e.g., the methods in 40 CFR 136, appendix A). The generally accepted practice followed by EPA is to verify calibration in a region where error is a constant proportion of the level being measured. This may not be the case if calibration were done at the minimum level.

A commenter stated that the MDL tests for Method 1613 use reagent water for tests of initial precision and recovery (IPR) and on-going precision and recovery (OPR), and that this practice is inappropriate for methods that must rely on extensive cleanup. Reagent water is water in which the analyte(s) of interest and interfering compounds are not detected by the method being used. EPA disagrees that reagent water is inappropriate for the IPR, OPR, and other tests. EPA believes that in the case of dioxin in drinking water, reagent water and drinking water are nearly equivalent matrices, in that the concentrations of potentially interfering compounds in drinking water are extremely low.

A commenter stated that allowing the analyst the flexibility to modify the method may adversely affect method performance on real world samples, and cited as examples that the performance test solution used to evaluate the particular columns in Method 1613 will not work with other columns, and that reducing the solvent volumes to elute the dioxin from the AX-21 cleanup column would prevent analysts from meeting the detection limits specified in the method. EPA disagrees. In developing and promulgating the 40 CFR part 136, appendix A methods, EPA has received comments in the past similar to this one that the methods should allow no flexibility in procedures [49 FR 43246]. EPA also received comments that there should be great leeway to modify the methods [49 FR 43245]. EPA's general response to those comments and to this comment is that flexibility is permitted only in discretionary elements of the test procedures, and that the data generated must meet all stated performance criteria.

For the specific examples that the commenter cited, EPA believes that the requirement for an alternate gas chromatographic column to meet not only the specifications for the performance test solution but also to meet the relative retention time criteria in Method 1613 effectively precludes any column with inferior performance, and that reducing the solvent volumes used with the AX-21 column to the point

where native dioxin becomes non-detectable would probably cause the recovery of the labeled compounds to fall below the recovery specifications in the Method; therefore, this would not be allowed.

EPA notes that the objective of permitting flexibility in certain discretionary parts of its methods is to allow for improvements in technology while requiring all performance specifications in the method to be met.

A commenter included with its comments approximately 40 pages of suggested technical modifications of Method 1613 to improve the reliability of the Method. EPA appreciates these suggestions. This commenter has participated in EPA's validation studies, has conducted validation studies of its own, has scrutinized the details of Method 1613 and other EPA methods, and has provided many valuable suggestions for improvements to these methods. EPA has considered all of these suggestions, as well as the suggestions of others, in its continuing evolution and upgrading of analytical methods, and shall continue to work with all interested parties to assure that these methods are as state-of-the-art as possible. Many of the suggestions relate to analyses of more complex non-drinking water matrices and are not relative to analysis of drinking water samples.

1613 Inter-laboratory study. A commenter said that EPA had not completed its inter-laboratory study of Method 1613 at time of proposal of the drinking water regulation for dioxin, and that EPA is premature in proposing Method 1613 without validating it first. EPA has relied only on the MDL studies on Method 1613 in determining the MDL and the PQL. Inter-laboratory validation studies are on-going and EPA will make them public when complete. However, EPA is not required by statute or policy to use inter-laboratory data to establish MDLs or PQLs.

Two commenters stated that EPA's inter-laboratory study used extracts of samples but not real-world samples. Both commenters are correct. However, this rule relies on an MDL study as the basis for the PQL, and not the inter-laboratory studies. Therefore, this is not a relevant issue for this rule. EPA used extracts of real-world samples because the shipment of large volumes of dioxin-containing water both intra- and inter-nationally was deemed to be too great a risk to human health and the environment, and because of the difficulty in producing a homogeneous mixture of dioxins in such large water volumes. EPA understands the

commenters' argument and concerns that performing an inter-laboratory study on extracts of water rather than water itself could possibly result in less bias and greater precision than if water had been used, but EPA believes that the risk of using raw waste water samples was unacceptable. EPA has recently collected and received a large volume of data on application of Method 1613 to paper industry wastewater and believes that the matrix effects associated with extraction of dioxin from water are fairly well quantified at this point. EPA believes that its international inter-laboratory validation study will be valuable in assessing method and laboratory performance, even though the study will not be conducted on raw wastewater. However, the complex matrix effects these data are intended to identify and help resolve are not relevant to drinking water samples.

SDS extraction. A commenter stated that the Soxhlet/Dean-Stark (SDS) extraction procedure for solids has only been tested to a limited extent on one municipal sludge. The commenter was correct at the time of this comment in that EPA had performed limited testing of the SDS extraction procedure on a limited number of samples. Since that time, EPA and others have extracted many samples using the SDS technique, and although some data show that some of the higher isomers and congeners of dioxin may not be extracted as efficiently as other extraction techniques, EPA has not confirmed these results. However, SDS extraction is not a method that would be used on drinking water samples, and so this comment is not relevant to the present rulemaking.

A commenter noted that use of liquid-solid extraction using 3M's Empore Disk is approved by EPA for Method 525.1, and is included in dioxin Method 513. The commenter suggested that EPA include the option of using the Empore Disk in Method 1613. EPA is currently evaluating the Empore disk as an extraction device for aqueous samples in Method 1613. EPA's Environmental Monitoring Systems Laboratory in Cincinnati, Ohio (EMSL-Ci) has performed extensive testing of liquid-solid extraction devices. EPA will continue to study the Empore disk and similar devices because of their potential for reducing solvent use in the laboratory, and will incorporate such devices into Method 1613 and other EPA methods if the performance of these devices is demonstrated to be equivalent to extraction devices presently in these methods. Nationwide

application for an alternate test procedure may be made under 40 CFR 136.5.

Labeled compound recovery. A commenter stated that recovery of labeled compounds in Method 1613 do not adequately correct for incomplete recovery of the native analytes because it is nearly impossible to spike the labeled compound into the sample in such a fashion that it distributes itself identically to the native analyte. EPA has chosen the isotope dilution technique for quantification because it is the most precise analytic technique currently available to measure dioxin. EPA is aware that in some instances the labeled compounds are not distributed identically to the native analytes, but believes that the advantages of the isotope dilution technique far outweigh any limited imprecision and reduced accuracy that may occur when external standard quantitation techniques are used. Nearly all analytical methods for dioxin employ isotope dilution to provide the highest accuracy and greatest precision.

Method Detection Limit (MDL) and minimum level. A commenter stated that Method Detection Limits (MDL's) of 5 and 10 ppq for Methods 1613 and 513, respectively, have not been demonstrated and that it is not possible for even the best laboratories to attain the MDL developed by EPA. EPA disagrees. EPA has now demonstrated that the MDL = 5 ppq using Method 1613, as described in the NOA.

A commenter stated that the proposed standard for dioxin is based upon detection limits associated with outmoded analytical methods that are thousands of times less sensitive than the most advanced methods available, that methods developed by Christoffer Rappe, University of Umea, Sweden are capable of detecting TCDD at 0.001–0.020 ppq in drinking water, and that Canadian methods achieve MDL's of 2 ppq in pulp mill effluents and could be extended to achieve 0.2 ppq in drinking water. EPA is aware that it is possible to achieve lower detection limits by revising the dioxin methods to use sample volumes 10 to 1,000 times (or more) larger than the existing methods. At present, most dioxin methods employ a one liter sample. This sample is shipped from field locations to laboratories that have HRGC/HRMS instruments. Samples will need to continue to be shipped from remote locations to laboratories. Most sample shipments are by overnight courier so that the samples can be maintained refrigerated from the time of collection until extraction. Shipping 10 to 1,000

liters presents unique logistics problems and is prohibitively costly (a 1,000 liter sample weighs approximately 2,500 lbs., and costs $1.50/lb. to ship for a total of $4,500 per sample). Also, while large volume samples might theoretically result in a lower MDL, increased interferences are likely to result. EPA is aware of no data demonstrating that lower MDLs may be achievable. An alternative would be to collect the samples on a liquid-solid extraction device at the remote location and ship the device to the laboratory. However, EPA has not developed or validated this sampling means at this time. EPA is aware of the methods proposed for regulatory use in Canada, and believes that the improvements in sensitivity suggested by the commenter are simply the result of differences in terminology and reporting practices. The Canadian methods use the term "MDL" to mean the sample-specific detection limit that is calculated solely on the basis of signal-to-noise measurements. In contrast, EPA uses the term MDL to refer to the statistically determined value that results from replicate measurements, as described in 40 CFR part 136, appendix B. EPA will continue to study devices and procedures for lowering the detection limit to levels commensurate with the Agency's measurement and regulatory needs.

1613 Method Detection Limit (MDL) study. A commenter stated that the 5 ppq MDL in Method 1613 was calculated from a single-shot experiment that does not represent a real work estimate of the MDL. It alleges that a real world estimate of the MDL is at least 10 ppq based on the 104 mill study and an estimate by Georgia-Pacific. EPA agrees that the MDL in Method 1613 was obtained by a single use of the MDL procedure [40 CFR part 136, appendix B]. As described in the proposal of Method 1613, the MDL procedure was followed as prescribed, with a result of 5 ppq. EPA has reviewed the data submitted by the contract laboratory that performed the MDL procedure and believes that the tests were performed properly and that the 5 ppq MDL is valid. EPA believes that if the MDL procedure were performed in other qualified laboratories, similar results would be obtained using Method 1613, although some laboratories might obtain slightly higher or slightly lower results. However, the MDL is by definition a single laboratory single operator concept. EPA is unaware of any samples in the 104 Mill study that were analyzed at least seven times, or that conformed to other requirements of the procedure for determining the MDL. The

commenter provided no specific data for analysis. Moreover, the 104 Mill study analyses concern pulp, sludge and industrial wastewater matrices and so the MDL derived in that study is not necessarily the lowest that could be obtained in samples that more closely resemble drinking water matrices.

Two commenters claim that the MDL study cited was conducted with reagent water and, therefore, the MDL study is not relevant. As EPA stated in its response above to the use of reagent water for initial and on-going precision and recovery and other quality control tests, EPA believes that in the case of dioxin in drinking water, reagent water and drinking water are nearly equivalent matrices, in that the concentrations of potentially interfering compounds in drinking water are extremely low.

A commenter said that no data are presented in the Federal Register notice [56 FR 5090] other than for reagent water. Therefore, the proposed minimum levels for solid matrices are insupportable. For the purpose of the regulation of dioxin in drinking water, data on matrices other than on reagent water or drinking water are unnecessary.

A commenter said that the MDL experiment is inappropriate due to the high spike levels chosen for the study, that the variability increases as the concentration levels approach the MDL, and that the only way to truly determine the MDL is to perform the experiment at the exact level of the MDL. EPA notes that the 25 ppq level was chosen as described in EPA's proposal of Method 1613 [56 FR 5095]. As stated earlier, EPA believes that its contract laboratory followed the MDL procedure correctly, including the use of 25 ppq as the spiking level. EPA agrees that the variability increases as the concentration levels approach the MDL. However, one of the tenets of the concept of the MDL is that the relationship between the level and the standard deviation of the measurement becomes approximately constant in the region of the MDL and the spiking level is not critical in this region. In addition, EPA believes that spiking at too high a level will tend to overestimate the MDL rather than underestimate it. EPA is also in the process of contracting for additional MDL studies in a variety of matrices and at other spiking levels appropriate to the matrices. These data will be made available at a later date.

Two commenters stated that it is well known that a break in the calibration curve occurs at approximately 5 ppq. Consequently extrapolation from 25 or

12 ppq to 5 ppq is not technically valid. Extrapolation must be made at or below the break point. One of the commenters stated further that extrapolation of the instrument calibration far beyond demonstrated performance is not sound science and provided a graph showing relative standard deviation as a function of corresponding effluent concentration for native dioxin in calibration standards. EPA agrees that calibration error increases as concentration levels approach the MDL, but believes that the measurement of the MDL in Method 1613 was made in a valid region of the calibration curve and was made according to the MDL procedure, as detailed in the proposal of Method 1613 [56 FR 5095] and the support documents for the NOA. EPA has reviewed the graph provided by the commenter and believes that the graph supports the validity of an MDL of 5 ppq. The graph shows data points at equivalent concentrations of approximately 3, 5, 12, 100, 1,000 and 5,000 ppq, associated with relative standard deviations of approximately 16, 8, 7, 5, 2 and 2 percent, respectively. Calculating the relative standard deviation (RSD) of these values results in standard deviations of 0.48, 0.40, 0.84, 5, 20, and 100 ppq, respectively, for the concentrations. Assuming that the RSD's are the result of three replicate determinations, the Student's t multiplier used in the MDL procedure is 6.97, resulting in MDL values of 3.4, 2.8, 5.9, 35, 140, and 700 ppq. (If more than three replicates were used, the MDL values would be lower). These data clearly show that in the region of the MDL (2–10 ppq), the MDL is approximately constant, but rises rapidly as the spike level increases. Thus, the use of a high spike level would tend to overstate the MDL, the opposite of what is argued by the commenters. Further, the data provided clearly show that measurements can be made in the range of 5 ppq because data were reported in this range.

Two commenters stated that dioxin was not detected in one of seven replicates in EPA's test of the MDL for Method 1613. EPA believes that in EPA's studies of the MDL for Method 1613, EPA's contract laboratory performed the study improperly in its first attempt. In this attempt, the laboratory spiked the native analytes into the blank that was a part of the quality control associated with the MDL test. Also, as pointed out by the commenters, the laboratory failed to detect dioxin in one of the seven replicates. EPA rejected the data from this MDL study, and had the laboratory determine the MDL under the controlled

conditions that EPA requires. The MDL of 5 ppq that EPA states for Method 1613 is the result of the properly conducted study. EPA did not formally release the results of the improperly conducted study, but has made all results of all studies available to all interested parties.

MDL/PQL issues. A commenter said that the lowest level that can be measured is the PQL. EPA disagrees. EPA has demonstrated that measurements can be made as low as the MDL, but has defined the concept of the PQL as the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions [50 FR 46902]. Thus, the PQL provides an allowance for the degree of measurement precision and accuracy that EPA estimates can be achieved across laboratories. If EPA desires a level of measurement precision and accuracy that is high, the PQL is set slightly higher (on the order of 10 times the MDL); whereas if the Agency desires a slightly lesser level of measurement precision and accuracy (in exchange for reduced health risks), EPA will set the PQL level somewhat lower (on the order of 5 times the MDL), but EPA believes that measurements can be made in the range between the PQL and MDL.

A commenter stated that finalization of the PQL should await completion of an appropriately designed inter-laboratory study because the PQL is intended to reflect performance of multiple laboratories. The commenter also noted that the preferred method of determining the PQL would be to utilize performance evaluation data from as many labs as possible. EPA believes that inter-laboratory studies, whether method validation or performance evaluation, are useful in establishing the PQL, but also believes that a multiplier of 5–10 times the MDL is an effective way to establish the PQL. In estimating the PQL, EPA takes into consideration all data available, including single laboratory, multi-laboratory, performance evaluation, and other data, as well as regulatory needs to protect human health and the environment. In the regulation of dioxin in drinking water, EPA has reviewed the data from its study of Method 1613, as well as data submitted by commenters. EPA has established the PQL for this rule after a review of technical data from method studies and from health risk considerations.

A commenter said that decreasing the PQL from 50 ppq to 30 ppq represents a very slight decrease in the level of risk that does not justify the drastic increase

in the level of uncertainty that would occur. EPA disagrees that there is a drastic increase in the level of uncertainty between 50 and 30 ppq. As the data submitted by the commenter demonstrate, the uncertainty attributable to calibration increases from approximately six percent to approximately seven percent when the level decreases from the equivalent of 50 to 30 ppq.

A commenter stated that it is a longstanding practice within the scientific community to use a 3-fold multiplier in establishing the limit of quantitation. The American Chemical Society (ACS) uses the concepts of the Limit of Detection (LOD) and Limit of Quantitation (LOQ) in discussions of the lower limits of analytical measurements. The LOD is approximately equivalent to EPA's MDL and the LOQ is approximately 3.3 times the MDL. As EPA has stated in previous discussions of the PQL [50 FR 46902], the MDL and LOQ are single laboratory concepts, whereas the PQL is the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. EPA uses a multiplier of 5 to 10 times the MDL as well as other factors to establish the PQL. EPA is presently in the process of reviewing its approach to establishing the limits of analytic chemistry for drinking water samples and the use of this information in setting drinking water standards. EPA may propose revisions to its general approach in a later Federal Register notice. The ACS concepts are among those that will be considered in this process. EPA will review its MCLs at that time to determine whether revisions are appropriate.

A commenter stated that the PQL should be set at 10 times the MDL since the carcinogenic risks do not justify less precision in dioxin measurement. As EPA has noted in response to other comments, EPA has set the PQL at approximately five times the MDL based on technical and health risk considerations. The PQL is a regulatory tool that may include consideration of health risk. EPA also reiterates that the precision of the dioxin measurement is not significantly degraded between 50 and 30 ppq.

c. *Detection and quantitation levels; laboratory performance criteria.* Many comments were received on EPA's procedures for determining MDLs and PQLs. Calculation of method detection limits (MDLs) by procedures set forth at 40 CFR Part 136 Appendix B is understood and generally accepted by

the laboratory community. A few commenters wrote that since some MDLs cited in EPA methods are a one time determination by one analyst, the results may not generally be achievable by the number of laboratories needed to handle compliance monitoring on a routine basis. EPA believes that laboratory performance improves as an analysis progresses from being novel to routine. The purpose of the PQL concept is to allow for this inter-laboratory variability and ensure that the majority of good laboratories can adequately measure contaminants. EPA has also provided relief for most contaminants in today's rule by permitting performance evaluation samples to be judged by the results of the group of laboratories participating in each study rather than on an absolute scale (i.e. the pass criteria are two standard deviations from the average result rather than within a fixed ±percentage of the spiked concentration).

The selection of practical quantitation levels (PQLs) has been discussed at 55 FR 30370 and references therein. EPA received comments on PQLs identical or similar to those received and responded to in earlier rules [55 FR 30370, and 56 FR 3547–3552 and 30269–30271]. Some commenters on the July 1990 proposal wrote that some PQLs were too low for most laboratories to quantify a contaminant with acceptable precision because EPA relied too much on performance by the "best" laboratories in setting the PQLs. Some commenters

objected to the PQL for dioxin that was proposed at five times the method detection limit. They suggested all PQLs be ten or more times the MDL even if this required that a maximum contaminant level (MCL) be increased; EPA disagrees. EPA recognizes that use of a five-fold multiplier, rather than ten-fold, may result in some loss of precision and accuracy in performing analyses. However, EPA believes it is sometimes appropriate to accept somewhat greater imprecision and inaccuracy when necessary to achieve health risks within EPA's target risk range. EPA makes such judgments on a case-by-case basis.

Other commenters stated that some PQLs were too high, especially for contaminants with zero or very low maximum contaminant level goals. These commenters suggested that PQLs and MCLs could be lowered significantly to reduce risk, thereby allowing only the best laboratories to perform compliance analysis. However, EPA believes this is impractical, due to the large number of compliance samples that are required to be analyzed by these rules.

In response to this interest in detection and quantitation levels, EPA, the American Chemical Society (ACS) and the American Society for Testing and Materials (ASTM) are working on standard definitions of analytical detection and quantitation levels for chemical analyses in any matrix. The definitions, if adopted by EPA, would be only a part of the process used to

determine the feasibility of measuring a contaminant with acceptable precision at the MCL. The Agency is also developing criteria to define what data should be collected to set interlaboratory performance standards.

EPA has determined, however, that it is appropriate to set PQLs for today's contaminants using the procedures discussed in the proposal (55 FR 30370 and references therein) rather than waiting for the results of the new definitions. The maximum contaminant level goal (MCLG) for several of the organic chemicals in today's rule is significantly greater than the MDL listed for each contaminant in the EPA methods. This means setting MCLs equal to MCLG does not pose the same problem as when reliable detection and quantification is desirable near or below MDLs.

For sixteen regulated organic chemicals in today's rule, the PQLs are based on laboratory performance data. As discussed earlier, considerable variation in interlaboratory performance was observed. For this reason, the PQLs for benzo(a)pyrene and 2, 3,7,8-TCDD are respectively estimated at ten times and five times the method detection limit (as defined at 40 CFR part 136, appendix B). Table 15 lists MCLs, PQLs and laboratory acceptance limits for each organic contaminant. The ranges of concentrations included in EPA's laboratory performance samples are also listed.

TABLE 15.—MCLs, PQLs AND ACCEPTANCE LIMITS DETERMINED FROM LABORATORY PERFORMANCE STUDIES

Contaminant	MCL (mg/l)	PQL (mg/l)	±Acc. Lim.
1,2,4-Trichlorobenzene	0.07	0.005	±40%.
1,1,2-Trichlorobenzene	0.005	0.005	±40%.
Benzo(a)pyrene	0.0002	0.0002	2 Std. Dev.
Dalapon	0.2	0.01	2 Std. Dev/
Dichloromethane	0.005	0.005	±40%.
Di (2-ethylhexyl) adipate	0.4	0.006	2 Std. Dev.
Di (2-ethylhexyl) phthalate	0.006	0.006	2 Std. Dev.
Dinoseb	0.007	0.002	2 Std. Dev.
Diquat	0.02	0.004	2 Std. Dev.
Endothall	0.1	0.09	2 Std. Dev.
Endrin	0.002	0.001	±30%.
Glyphosate	0.7	0.06	2 Std. Dev.
Hexachlorobenzene	0.001	0.001	2 Std. Dev.
Hexachlorocyclopentadiene	0.05	0.001	2 Std. Dev.
Oxamyl (Vydate)	0.2	0.02	2 Std. Dev.
Picloram	0.5	0.001	2 Std. Dev.
Simazine	0.004	0.0007	2 Std. Dev.
2,3,7,8-TCDD (Dioxin)	3×10^{-8}	3×10^{-8}	2 Std. Dev.

In the July 1990 proposal only the PQLs for the VOCs were based on an analysis of EPA-sponsored laboratory performance studies. The remaining PQLs were calculated as multiples of the MDL. More performance study data,

which was cited in the November 29, 1991 notice, has now been obtained and evaluated. The final acceptance limits to successfully analyze the samples were generally set at plus or minus two standard deviations (±2 std. dev.) from

the average value measured in each study.

With the exception of endrin and three volatile organic chemicals (1,2,4-trichlorobenzene, 1,1,2-trichloroethane, and dichloromethane), EPA agrees with

commenters that the performance by the current pool of laboratories does not warrant setting pass/fail criteria within fixed plus or minus percentage limits of the true concentration and acceptance limits for the other organic contaminants in today's rule remain at ±2 standard deviations. EPA disagrees with the comment that regulation be delayed until fixed acceptance ranges can be determined by interlaboratory performance. EPA believes performance will improve as laboratories routinely use a method to maintain certification for compliance monitoring analyses. The new methods are based on the same basic analytic techniques as many existing methods (such as GC, GC-MS, HPLC). EPA's experience in applying these techniques to other analytes has been that laboratory proficiency improves as laboratories become more experienced with the basic technique and specific individual methods.

Although the data are insufficient to change the proposed certification acceptance limits, they are sufficient to examine the relationship between study-generated PQLs and PQLs calculated by multiplying MDLs by a factor. In today's rule, EPA has set PQLs for 16 organic contaminants after considering an analysis of the performance from EPA-sponsored laboratory studies and MDL data. In most cases the PQLs are ten times the MDL. For four contaminants, the PE data were adequate for establishing the PQLs. For the remainder, PQLs were established on the generalization of 10 times the MDL. For many of these contaminants, a limited number of laboratories participated in the PE studies, and EPA therefore believes these data do not adequately represent likely performance over time. For other cases, while there were a considerable number of laboratories participating, the regression-derived acceptance limits were broad (> ±50%), and the PQL was based on 10 times the MDL, with acceptance limits set at ±2 standard deviations, to allow for improvement in the future. EPA found that federal and State laboratories, which were more experienced with the methods performed better. EPA therefore believes the other laboratories' performance will improve over time and use of 10 times the MDL to set the PQL is appropriate.

For dioxin (PQL=5 MDL) and benzo(a)pyrene (PQL=10 MDL), PQLs could not be derived from an analysis of the limited laboratory performance database. The commenter correctly notes that in most studies, benzo(a)pyrene was not tested near the final maximum contaminant level of 0.0002 mg/1. However, in the November 29, 1991 notice and in today's rule, EPA discusses a two-laboratory study of this contaminant. The precision obtained in samples spiked at 0.0002 mg/1 was excellent—±6 percent or better. A similar study, which is discussed in today's rule, for dioxin using Method 1613 was conducted with good results. Thus, the PQL for dioxin and benzo(a)pyrene are today specified respectively as five and ten times the MDL.

The final PQLs for di(2-ethylhexyl]adipate and di(2-ethylhexyl]phthalate are set at ten times the MDL. This is consistent with EPA's general guidelines that calculated PQLs be equal to five to ten times the MDL. The commenter refers to the relatively poor performance in some of EPA's cited studies. However, in the November 29, 1991 notice and in today's rule, EPA discusses an improvement in the Method 506 eluant mixture, which has been tested in samples spiked near the final maximum contaminant levels. EPA believes these data warrant setting a PQL at ten times the MDL.

EPA notes that PQLs that are based on an evaluation of the concentration at which about 75 percent of the laboratories participating in a study can successfully analyze a sample use a criterion that is more stringent than setting a pass criterion of ±2 std. dev. Using this approach, the final PQLs for volatile organic chemicals are very close to ten times the MDL. This is consistent with the performance observed with other regulated volatile organic chemicals, all of which can be measured in the same sample by an identical analytical procedure. Since analyses for dioxin, pesticides and other organic chemicals in today's rule use several different analytical techniques, EPA expected laboratory performance would be less homogeneous than for the VOC chemicals, which used the now-routine purge and trap method. Use of study-dependent laboratory criteria is consistent with the requirement to achieve the lowest feasible MCL.

EPA disagrees that performance sample data need to be normally distributed in order to proceed with a determination of the suitability of a method for compliance measurements. It is not practical or necessary to benchmark interlaboratory performance on anything but a standard matrix. Each analytical method notes if and how the analyst should check a compliance sample or laboratory reagents for possible interferences. As discussed in today's rule, the available data indicate that laboratories have done so even with potentially difficult analytes such as dichloromethane.

EPA agrees with the comment that when analytical variability poses a problem, the system should have the opportunity to use multiple samples and average the results. EPA's monitoring requirements already provide this relief. The requirements permit confirmation of sample results, and the elimination (with State concurrence) of spurious analytical results. And more than one confirmation sample may be taken, provided the State concurs.

EPA notes that for most of the analytes presented in the table with relatively high confidence intervals, the PQLs and MDLs are significantly less than the final MCLGs and MCLs, so imprecision of the analysis is not as likely to lead to resource-wasting false positives.

The PQLs for most of the contaminants are identical to the PQLs proposed on July 25, 1990. The PQL for 2, 3, 7, 8–TCDD decreased based on an evaluation of data from an interlaboratory study that used Method 1613. The data were cited and discussed [56 FR 60952–60953] in the November 29, 1991 notice of availability.

For the reasons cited elsewhere in this rule and in the July 25, 1990 proposal [55 FR 30416], the final MCLG for 2, 3, 7, 8–TCDD (dioxin) remains at zero mg/l, and the final PQL is estimated as five, rather than 10, times the MDL. As discussed in the November 29, 1991 notice, MDLs of 6×10^{-9} mg/l and 4×10^{-9} mg/l were obtained with a precision of ±12% in an EPA-sponsored study. Considering the zero MCLG, the high relative health risk, and the low probability of occurrence in finished drinking water, the final PQL has been set at five times the average of the two MDLs. The average MDL is 5×10^{-9} mg/l—five times this MDL is 2.5×10^{-8} mg/l, which rounded up becomes the final PQL of 3×10^{-8} mg/l. The final MDL is 50% lower than the proposed MDL of 10×10^{-9} mg/l. The final PQL for dioxin is 40% less than the proposed PQL of 5×10^{-8} mg/l.

The important use of laboratory performance data is to help EPA set fixed ranges of ± acceptance limits (Table 15) for laboratories to obtain and maintain certification. For fourteen of the organics covered by today's notice, EPA has set the acceptance limits for certification samples at two standard deviations based on performance sample study statistics rather than defining fixed acceptance limits.

These limits will permit a reasonable number of laboratories to obtain

certification for compliance monitoring analyses while ensuring continued progress toward more efficient analysis.

Laboratory performance data for the remaining five organic contaminants were obtained in the following studies, which were also cited in the November 29, 1991 notice. In the first study, the lowest concentration of benzo(a)pyrene tested in an EMSL study was 0.002 mg/l, which is ten times greater than the proposed MCL. Rather than extrapolate these data, two EPA laboratories tested Method 550 for benzo(a)pyrene at the proposed MCL of 0.0002 mg/l [USEPA, 1991c]. They achieved a very good precision of ±6 percent or better. The second study concluded that the precision for adipate and phthalate analysis with Method 506 was relatively poor in EMSL PE studies [USEPA, 1991c]. With the solvent changes discussed in Section III–B–3a, an EMSL laboratory obtained very good precision of ±6 percent or better in samples spiked near the MCLs. Based on these results EPA is citing Methods 506, 550 and 550.1 as compliance methods in today's rule, and is permitting individual performance evaluation sample study statistics to determine the acceptance limits (ranges) by setting them at two standard deviations around the average concentration (Table 15).

For endrin and the volatile organic chemicals, an analysis of laboratory performance evaluation data, the most recent of which were cited in the November 29, 1991 NOA, affirms that laboratory performance warrants using fixed limits of ±30 percent for endrin. The data also support using the fixed acceptance limits of ±40 percent for three volatile organic chemicals included in today's rule— dichloromethane, 1,2,4-trichlorobenzene and 1,1,2-trichloroethane. These are the same limits listed in Table 16 of the July 25, 1990 notice.

Several commenters on the NOA data for the SOC contaminants expressed concern about broad confidence intervals (near ±100 percent) and stated doubts about PQLs based on such wide bands. EPA agrees that the data for some contaminants showed broad acceptance bands, and for those contaminants, EPA has established acceptance limits as ±2 standard deviations of the data developed in PE studies. As laboratory performance with these methods improves, as is EPA's experience with new methods, the confidence intervals will narrow.

4. *Laboratory certification.* Several commenters expressed concern about the resources needed and the time constraints to achieve full certification prior to the initial monitoring period for newly regulated contaminants. EPA understands that certification for all parameters in time to comply with the initial monitoring deadlines (specifically, the January 1993– December 1995 period in today's rule) may present some difficulties in some areas. To alleviate this, EPA is recommending that States and Regions grant provisional certification, but only for recently regulated analytes. The provisional certification criteria are not regulatory in nature. Guidelines for granting provisional certification are described in EPA's "Manual for the Certification of Laboratories Analyzing Drinking Water" [USEPA, 1990m].

States and Regions are encouraged to begin certifying laboratories for analytes as soon as MCLs and certification requirements for those analytes have been promulgated. It is not necessary to wait for MCLs to become effective or for the State or Region to become certified. Under the Certification Manual, a State is to grant a laboratory provisional certification only for newly regulated analytes until the next regularly scheduled on-site audit after the effective date of the MCLs or until the end of the first monitoring period, whichever comes first. Also, according to the Certification Manual, in order to be granted provisional certification a laboratory should currently be certified to test for other drinking water parameters, pass an annual performance evaluation sample containing the analytes of interest, and meet all the other criteria stated in the rule. States may add additional requirements that they deem appropriate. In addition, States may set criteria for certifying a laboratory for the measurement of dioxin (2,3,7,8–TCDD) with EPA Method 1613.

EPA wishes to clarify the effective date of promulgated analytical methods in this rule. A promulgated method or method update must be used for those analytes for which it was promulgated as soon as the MCLs become effective, which is usually 18 months after promulgation. However, the methods may and should be used starting 30 days after promulgation of the rules for analyzing samples. This will enable laboratories to be well prepared and at least provisionally certified when the MCLs and monitoring requirements become effective.

5. Selection of Best Available Technology

a. *Inorganics.* On July 25, 1990, EPA proposed the best available technologies (BATs) for the removal of the five inorganic contaminants from drinking water [55 FR 30416]. Today's notice finalizes these determinations. Table 16 summarizes the final BATs for the five inorganic contaminants.

TABLE 16.—FINAL BAT FOR INORGANIC CONTAMINANTS

Contaminant	BAT [1]
Antimony	C/F; RO.
Beryllium	AA; IE; RO; LS; C/F
Cyanide	IE; RO; CH.
Nickel	IE; RO; LS.
Thallium	AA; IE.

[1] Best Available Technology (BAT):
AA = Activated Alumina.
IE = Ion Exchange.
LS = Lime Softening.
RO = Reverse Osmosis.
C/F = Coagulation/Filtration.
CH = Chlorine Oxidation.

The BATs presented in this notice are the same as in the proposal with one exception: ion exchange for cyanide removal is amended to require pH adjustment for better removal efficiency. This issue is discussed below in further detail with the discussions of the other major concerns expressed during the public comment period for the proposed rule regarding the BATs for the IOCs.

(1) *BAT field demonstrations.* Several commenters stated that the proposed BATs have not been demonstrated specifically for some of the inorganic contaminants under field conditions. These commenters were concerned that the reliance upon bench-scale and pilot-scale data in the absence of field studies might not meet the requirements of BAT for these contaminants under section 1412(b)(5) of the SDWA.

The Agency does not believe that the SDWA requires field studies as a prerequisite to establishing BAT for a contaminant. The SDWA directs EPA to set the MCL as close to the MCLG as "feasible." The SDWA defines "feasible" as "feasible with the use of the best technology which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, [is] available (taking costs into consideration)." Section 1412(b)(3)(D). EPA interprets this provision to require field trials for a technology, not for the application of that technology to each individual contaminant. Consequently, EPA has not required full-scale field validation of a technology's feasibility for treating a specific contaminant if its effectiveness has been demonstrated at bench or pilot scale for that compound. The technology, however, must reasonably be expected to perform in a similar manner under field conditions regardless of aberrations due to scale-u factors.

It should also be noted that many of the 83 contaminants for which Congress required EPA to establish NPDWRs by June 19, 1989 had never been regulated by EPA or treated by public water systems. Thus for many of the contaminants which Congress required EPA to regulate, the data which the commenter asserts are a prerequisite to selecting a technology as BAT do not yet exist. The commenter's arguments suggest that Congress required EPA to regulate many new contaminants within 3 years of the 1986 amendments but effectively precluded EPA from selecting any technologies as BAT for the regulations. Therefore, EPA believes it is appropriate to consider pilot plant and laboratory studies to project the removal efficiencies for these inorganics that would have been achieved by technologies that have been in full-scale use by public water systems for other similar contaminants. A detailed discussion of the efficiencies of each of the treatments can be found in the July 1990 proposal and in the "Technology and Costs for the Removal of Phase V Inorganic Contaminants from Potable Water Sources" [USEPA, 1990b].

While some of the treatments listed as BATs in Table 16 are not currently in full-scale use to treat specifically for the inorganic contaminants in today's notice, they are demonstrated technologies currently in use to treat a variety of drinking water contaminants, including previously regulated inorganic contaminants. Further, in each case, high quality bench- or pilot-scale data obtained under verifiable conditions which replicate typical drinking water treatment conditions have been provided. These data confirm that the treatment efficiencies of these technologies are high and that these technologies may be properly designated as BAT for the inorganic contaminants.

(2) *Potential for antimony leaching from tin/antimony solder.* Several commenters were concerned that antimony could leach from tin/antimony solder joints similar to lead leaching from lead/tin solder joints.

EPA has determined that antimony leaching from tin/antimony solder does not present a contamination problem. EPA has based this determination upon a theoretical analysis of the potential for leaching and on three studies that investigated antimony levels in water in contact with tin/antimony-soldered copper pipe joints [Herrera et al., 1981, Subramanian et al., 1991, and USEPA, 1988a].

When different types of metals are in contact with each other, galvanic corrosion can occur. In a galvanic couple, one metal will serve as the anode, which will deteriorate, and the other metal will serve as the cathode. For copper pipes soldered with either lead/tin solder or tin/antimony solder, three galvanic couples can exist. For lead/tin-soldered copper pipe joints, the three couples which exist are: copper-tin, copper-lead, and lead-tin. The strongest galvanic couple of these three will be the copper-lead couple and lead will serve as the sacrificial anode. Thus, galvanic corrosion would promote lead leaching from a lead/tin-soldered copper plumbing joint. For the tin/antimony-soldered copper pipe joint, the three couples which may exist are: copper-antimony, copper-tin, and tin-antimony. The strongest galvanic couple of these three will be the copper-tin couple and tin will serve as the sacrificial anode. Thus, galvanic corrosion would promote tin leaching, rather than antimony leaching, from a tin/antimony-soldered copper pipe joint and very little antimony would be expected to leach. In addition, tin can be passivated by tin oxide, which could form a passivating film to further inhibit antimony leaching from a tin/antimony solder joint.

Laboratory experiments and field tests were conducted to verify the theory on the potential for antimony leaching from tin/antimony solder joints (Seattle Distribution System Corrosion Control Study: Volume III. Potential for Drinking Water Contamination from Tin/Antimony Solder prepared by Herrera et al. for USEPA (August, 1981) [Seattle, 1981] and also reported in Herrera et al., Journal of the American Water Works Association, July 1982) [Herrera et al., 1982].

The laboratory experiments evaluated antimony levels from tin/antimony-soldered copper coupons with stagnation times between one-half hour to 98 hours. Two coupons of pure antimony were also tested with a stagnation time of 70 hours for comparative purposes. The coupon tests demonstrated that antimony dissolution was several orders of magnitude lower than the dissolution from pure antimony metal even though the stagnation time was longer (98 hours versus 70 hours). The highest antimony concentration observed in the tin/antimony coupon testing was 3.7 μg/1, which is below the MCLG promulgated in this noticed for antimony. In addition, tin oxides were found adhering to areas on the solder, which may provide additional inhibition of antimony leaching from tin/antimony solder.

Field tests were conducted at the University of Washington where tin/antimony solder has been used for building plumbing systems since 1968. Samples (0.9 liter) were taken at the point where the distribution system entered the building to obtain the characteristics of the inflow water. Several commenters stated that these were the only type of samples taken and claimed that the study did not evaluate the leaching potential of the plumbing. However, overnight standing samples (0.9 liter) were taken at the tap located the furthest distance from the entry point to the building. The plumbing systems ranged from 1 to 10 years in age. Thus, the contribution of antimony leaching from tin/antimony soldered copper pipe joints was evaluated by comparing the results from the overnight tap sampling with the building inflow sampling results. A difference in antimony concentrations between the overnight tap sample and the building inflow sample was observed in only one of the eight buildings where sampling was conducted. The concentration of antimony in that overnight tap sample was below the MCLG. All of the other antimony concentrations were below the detection limit. In addition, tin oxide films were found on three solder joints which were removed from a building's plumbing system. These films could have contributed to the inhibition of antimony leaching from these joints [Herrera et al., 1981].

The commenters noted that the study conducted at the University of Washington evaluated only one type of water quality. However, Seattle's finished water quality, at the time of this study, was corrosive, yet significant antimony leaching from tin/antimony solder was not observed under these conditions. In fact, all of the antimony concentrations measured in this study were below the MCLG and most were below the detection limit. The amount of antimony leaching from tin/antimony solder would be even less in non-corrosive waters.

This was confirmed by another study which evaluated the impact of several water qualities on antimony leaching from tin/antimony solder with various stagnation times (Impact of Lead and Other Metallic Solders on Water Quality, prepared by Murrell for USEPA. July, 1988) [USEPA, 1988a]. In this study, a pipe loop was constructed with tin/antimony-soldered joints to evaluate the effect of water quality or antimony leaching from tin/antimony solder. Four waters with the following characteristics were evaluated with varying stagnation times to determine their effect on antimony leaching from tin/antimony solder: (1) pH between 5.1 and 5.3; (2) pH between 6.3 and 6.6; (3)

pH 7.4; and (4) pH between 8.5 and 8.6. The stagnation times evaluated in this study were 4 hours, 8 hours, 12 hours, 24 hours, and 4 weeks. Six samples were taken at each pH and stagnation time combination.

For the two higher pH ranges, where the pH was above pH 7.0, all of the samples had antimony concentrations below 4 μg/l for stagnation times up to 24 hours. All of the samples for the lowest pH range also had antimony concentrations below 4 μg/l for stagnation times up to 24 hours. For the second lowest pH range (pH between 6.3 and 6.6), results at 4 μg/l and above were observed at stagnation times below 24 hours. One of the six samples with a stagnation time of 12 hours exceeded the final MCLG and three of the six samples with a 24-hour stagnation time exceeded the MCLG. However, EPA believes that systems with such a low pH would likely fail to meet the requirements of the recently promulgated lead and copper rule (June 7, 1991, Federal Register [56 FR 26460]). Those systems would therefore likely need to increase the pH of the finished water to comply with that regulation. Finished water with a pH above pH 7 did not produce antimony concentrations above the MCLG in this study and this water quality is a likely minimum necessary to comply with the lead and copper rule.

EPA also believes that this study addresses several commenters' concerns about antimony leaching from newly soldered joints. The commenters apparently believe that antimony leaching from tin/antimony solder could be similar to lead leaching from lead/tin solder and thus were concerned that significant concentrations of antimony could leach from newly soldered joints. As discussed above, antimony leaching from newly soldered joints was *not* observed in non-acidic waters which will predominate as systems comply with the lead and copper rule requirements.

The effect of water quality on antimony leaching from tin/antimony solder was also investigated in Subramanian, Conner and Meranger, Journal of Environmental Science and Health, 1991 [Subramanian et al., 1991]. This study investigated the effect of three water qualities on metals leaching from four non-lead-based solders. The amount of metals leaching from newly soldered joints was evaluated using high purity, tap, and well water samples with various standing times. The pH of the high-purity water was 6.8. The pH and alkalinity of the tap water was 7.8 and 30 mg/l (as CaCO₃). The pH and

alkalinity of the well water was 8.1 and 155 mg/l (as CaCO₃).

The amount of antimony leached into samples was at or below the detection limit of 1.2 mg/l for standing times up to 7 days, regardless of the water quality. For the high-purity and well water samples, there was no detectable leaching of antimony with standing times longer than 7 days. However, the amount of antimony leached into tap water after 14, 28, and 90 days of contact was 2.0, 3.7, and 7.3 μg/l, respectively. EPA does not believe that such unusually long standing times are typically encountered in public water supplies. Thus, this study supports EPA's position that antimony leaching from tin/antimony solder joints should not be a problem.

(3) *Disposal of wash brines from ion exchange and reverse osmosis treatments in water-scarce areas.* Commenters expressed concerns regarding the potential costs associated with disposal of wastes (particularly brine wastes) generated by treatment processes which remove inorganics. Of particular concern are waste brines generated by reverse osmosis (RO) and ion exchange (IE) processes. One commenter expressed concern about the environmental impacts as well as the potential impact of waste water treatment on water conservation concerns in water-scarce regions. For example, reverse osmosis results in loss of a percentage of the influent water as brine.

EPA does not agree with the commenter's assertion that environmental impacts (discussed below) would be extreme if a low sulfate standard (i.e., 400 mg/l) were promulgated. The Agency believes that water wastage could be minimized by treating only a portion of source water containing elevated sulfate levels, blending the treated water with source water, and by further treating brine wastes. Waste volume reduction and waste handling options appear not to have been fully considered by commenters. Other very conservative assumptions were employed by the commenter which led to conclusions not shared by EPA. The commenter's assumptions include: An increase in Colorado River sulfate levels beyond recent historical levels; and the overall importance of that source to the Southern California supplier, when competing entitlements to that river source may diminish the supplier's share of available river water.

One commenter stated that there are potential economic impacts where limited disposal options exist. The

Agency agrees with the commenter that cheaper options (such as direct discharge into a receiving body of water) are not always available. For these reasons, EPA has included several waste treatment and waste disposal options in its analysis and incorporated costs for all projected systems in the Regulatory Impact Analysis (RIA) Document developed for this rule [USEPA, 1992d]. These costs are a substantial part of the overall estimated treatment costs for meeting the drinking water MCLs.

Commenters raised questions about competition for scarce water in certain regions, the need for source water protection measures (i.e., pollution prevention), and waste quantity and quality that may limit disposal options. EPA has addressed these concerns in this rulemaking and in previous actions (Federal Register, Vol. 56, No. 20, pp. 3553–3554) and does not believe that the data and assertions presented in response to the July 1990 proposal are sufficient to raise regulatory concerns.

(4) *Alkaline chlorination treatment for cyanide.* Several commenters were concerned about the potential for increased concentration of trihalomethanes resulting from the alkaline chlorination treatment for cyanide. For systems whose raw water has a high trihalomethane formation potential, EPA agrees that this treatment could exacerbate the problem. However, systems can choose to install ion exchange or reverse osmosis, which would be less likely to significantly increase trihalomethanes. As stated in the proposal, the highest observed occurrence level for cyanide in drinking water (8 μg/l) is considerably lower than the MCL for cyanide (200 μg/l). Therefore, EPA expects that few, if any, systems would need to install treatment for cyanide and that increased trihalomethanes resulting from a cyanide BAT is unlikely to be a widespread problem.

(5) *Ion exchange as BAT for cyanide.* Several commenters stated that anion exchange would not remove cyanide because at the near-neutral pH values for most drinking waters, cyanide is much more likely to be present as HCN rather than CN. EPA agrees with the commenters' assertions that anion exchange would only likely remove cyanide that is present as CN. EPA believes, however, that systems that need to can increase the pH of their water to further dissociate HCN to CN. The ion exchange data presented in the Technology and Cost Document indicate that ion exchange can efficiently remove dissociated cyanide [USEPA, 1990b].

Cyanide is dissociated at lower pH levels than those cited in some of the studies in the Technology and Cost Document. EPA has provided the treatment costs for pH adjustment (see Lead and Copper in Drinking Water as a Result of Corrosion: Evaluation of Occurrence, Cost and Technology, 1991 [USEPA, 1991a]). An option for systems using ion exchange for cyanide removal would be to adjust the pH to dissociate and remove the cyanide and then lower the pH somewhat prior to chlorination and distribution. EPA believes this approach to be a more effective way to address cyanide removal in waters with significant trihalomethanes (THM) formation potential than alkaline chlorination. Nevertheless, for the reasons provided in the discussion of alkaline chlorination, EPA does not believe that increased trihalomethanes resulting from a cyanide BAT will be a widespread problem when using that method.

(6) *Sulfate reverse osmosis costs.* Several commenters questioned why the total treatment costs for sulfate removal by reverse osmosis were lower than the total treatment costs for the inorganic contaminants in this rule. The MCLs proposed for sulfate were several orders of magnitude higher than the MCLs for the inorganic contaminants in this rule. EPA assumed that systems would blend a treated portion and an untreated portion to reduce the total production costs for sulfate. EPA believes that only in extreme cases would systems require both high removal efficiency and treatment of the entire influent flow. Thus, systems were only assumed to treat a part of the product water to remove sulfate rather than the entire product flow as is assumed in the T&C document for the other inorganic contaminants. However, as was noted in the July 1990 proposal, blending to reduce total treatment costs is an option for systems using RO for the other IOCs. Since a smaller volume of water is being treated, capital costs and operation and maintenance costs would be lower, resulting in lower treatment costs than estimated.

(7) *Sulfate ion exchange costs.* Several commenters questioned why the total production costs for sulfate removal by anion exchange were higher than the total production costs for cyanide removal by anion exchange. The difference in the total production costs for these two inorganic contaminants resulted from higher operation and maintenance costs for sulfate removal associated with resin regeneration. The increased regeneration costs are due to faster saturation of the resin because of

the significantly higher levels of sulfate that would be treated to meet the proposed MCL levels compared to the levels of cyanide.

b. *Synthetic organic contaminant.* MCLs In the 1986 SDWA amendments, Congress specified in section 1412(b)(5) that "Granular activated carbon is feasible for the control of synthetic organic chemicals, and any technology, treatment technique, or other means found to be best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon." On July 25, 1990, the Agency proposed the best available technology (BAT) for the removal of the 18 synthetic organic chemicals (SOCs) from drinking water [55 FR 30420]. Today's notice promulgates the final rule for these contaminants, including identification of the Bat. Table 17 provides a summary of the proposed and final BATs.

TABLE 17.—PROPOSED AND FINAL BAT FOR ORGANIC CONTAMINANTS

Contaminant	Proposed BAT	Final BAT
Di-(2-ethylhexyl) adipate	GAC/PTA	GAC or PTA
Dalapon	GAC	GAC
Dichloromethane	PTA	PTA
Dinoseb	GAC	GAC
Diquat	GAC	GAC
Endothall	GAC	GAC
Endrin	GAC	GAC
Glyphosate	GAC	OX
Hexachlorobenzene	GAC	GAC
Hexachlorocyclo- pentadiene	GAC/PTA	GAC or PTA
Oxamyl	GAC	GAC
Benzo (a) pyrene	GAC	GAC
Di-(2-ethylhexyl) phthalate	GAC	GAC
Picloram	GAC	GAC
Simazine	GAC	GAC
2, 3, 7, 8- Tetrachloro- dibenzo-p-dioxin	GAC	GAC
1, 2, 4- Trichlorobenzene	GAC/PTA	GAC or PTA
1, 1, 2- Trichloroethane	GAC/PTA	GAC or PTA

GAC—Granular Activated Carbon.
PTA—Packed Tower Aeration.
OX—Oxidation (Chlorine or Ozone)

With one exception, the BAT presented in today's notice is the same as proposed in July 1990. The exception is glyphosate. The BAT for glyphosate was proposed as granular activated carbon (GAC) but has been finalized as oxidation. This change is discussed below.

The BATs for organics in today's final rule listed in Table 17 are discussed in detail in the Technology and Cost (T&C) document contained in the rulemaking docket [USEPA, 1992e]. In the T&C

document the available technologies are discussed, a summary of the literature documenting treatment performance is provided, and the cost estimates of BAT are detailed. The information presented in the T&C document, including the availability of a technology, its performance, and an estimated cost of compliance of using the technology are all considered and form the basis for determining the final BATs for the SOCs in today's rule.

The following discussion addresses the major concerns expressed during the public comment period for the July 25, 1990 proposed rule regarding the proposed BATs for the SOCs.

(1) *BAT field evaluations.* A number of commenters expressed concern that the BAT proposed for the SOCs had not been demonstrated to be effective according to the criteria set forth by the SDWA. They recommended that the Agency conduct field testing of all the SOCs under various conditions to determine the effectiveness of the BATs as proposed.

The SDWA directs EPA to set the MCL as close to the MCLG as "feasible." The SDWA defines "feasible" as "feasible" with the use of the best technology . . . which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, [is] available (taking costs into consideration)." As mentioned above, EPA interprets this provision to require field trials for a technology, not for the application of that technology to each individual contaminant. Consequently, EPA has not required full-scale field validation of a technology's effectiveness for treating a specific contaminant if its effectiveness has been demonstrated at bench or pilot scale for that compound. The technology, however, must reasonably be expected to perform in a similar manner under field conditions after considering aberrations due to scale-up factors.

For three of the contaminants in the July 1990 proposal (di(2-ethylhexyl)adipate and endothall and 2,3,7,8-TCDD), EPA relied on model predictions based on the compounds' physical/chemical characteristics, to specify GAC as BAT. At the time of proposal, treatment performance data were not available due to analytical difficulties with (di(2-ethylhexyl)adipate and endothall. Since proposal, however, the Agency has obtained treatment performance data for these two compounds. The treatment performance studies and data for both (di(2-ethylhexyl)adipate, endothall are included in the Technology and Cost

Document contained in the rulemaking docket [USEPA, 1992e]. The results of the studies on these two compounds support earlier BAT determinations of GAC made using the model. Further, the SDWA states that GAC is feasible for the control of SOCs.

With respect to dioxin, there is a pilot-scale treatment performance study indicating removal of dioxin from Agent Orange using GAC [Chemical Eng., 1977]. This study has limited applicability since the solvent is not water, but due to the associated health risks during analysis of dioxin, the treatment performance of GAC was determined based solely on the model predictions.

The Agency is designating GAC as BAT for dioxin in today's rule in spite of the lack of performance data. GAC has been statutorily designated as "feasible for the control of synthetic organic chemicals" (section 1412(b)(5), SDWA) and the results from model predictions based on the physical/chemical properties of dioxin support this determination. In light of the SDWA statement that GAC is feasible and the fact that GAC has proven to be effective in the laboratory and under full-scale conditions for other synthetic organic contaminants of similar characteristics, the Agency believes it is appropriate to establish GAC as BAT.

Cost considerations. One commenter stated that a BAT must be evaluated and applied to site-specific conditions and that estimated costs might not be representative of actual operating conditions.

In response, costs at specific sites may be higher than estimated in the Cost and Technology Documents. The design and costs of the treatment technologies evaluated as part of the T&C document pertain to an average system (not worst case), and are meant to be used for a system's preliminary planning purposes, for generating national cost estimates and for determining affordability for typical systems. Worst-case cost estimates are not used because the Agency does not believe that such estimates would accurately represent the affordability of treatment for large water suppliers on a national basis. Individual systems should develop a more complete and detailed design and cost evaluation based on pilot-plant testing and site-specific considerations. The cost estimates presented in the T&C document provide a basis that can be used by any system regardless of water quality.

Use of other technologies. One commenter noted that treatment facilities are free to choose technologies

other than BAT to meet the MCL. Other technologies may be chosen in lieu of BAT because they may be more cost effective or better suited to the specific operating conditions of the particular site to meet the MCL. Making the choice not to use BAT, however, means that a system will not be eligible for a variance under SDWA section 1415. For example, if a facility does not install GAC where it is the designated BAT, but uses PAC instead, and fails to meet the MCL, the facility would not be eligible for a variance. On the other hand, the same facility may be eligible for an exemption under SDWA § 1416 if for example GAC could not be installed due to an inability to obtain financing and PAC was used instead, and the facility failed to meet the MCL.

EPA agrees with commenters that GAC, and any other treatment technology for that matter, can create problems if not properly maintained and operated. Again, technologies other than GAC, PTA or OX can be used if they seem better suited to site-specific conditions in order to achieve the MCL.

Carbon disposal costs. Some commenters were concerned that the cost of disposal of spent carbon was not taken into account at all in the costing assumptions for the design and operation and maintenance (O&M) for a facility. The cost of carbon "disposal" is essentially the cost of regenerating the spent carbon (and replacing the 12 to 15 percent lost in the process). For plants whose daily carbon use is less than 1,000 pounds per day, EPA assumes that the carbon would be regenerated off-site by the carbon supplier and that cost is included in the cost of replacement carbon. For plants whose carbon demand is more than 1,000 pounds per day, it is generally economical to regenerate on-site. The cost of the incinerator used to regenerate the carbon and its operation and maintenance costs are part of the facility capital and O&M costs already factored into total costs. The revised model that EPA now uses in developing costs [Adams and Clark, 1989] factors into total costs the expense of carbon regeneration and replacement.

When powdered activated carbon (PAC) is used, it is usually disposed of with the alum sludge in a sanitary landfill. Because this rule does not consider PAC to be BAT, EPA is not addressing the issue of PAC costs, including the costs of disposal.

PTA and air emissions. One commenter stated that it is possible to transfer risk from water to air when using PTA. As the commenter points out, there is a possibility of transferring the risk associated with VOCs from water

to air when using PTA as a treatment technology (and that increased costs may result from a requirement to also treat the PTA emissions). EPA agrees that control of such air emissions may be required by regulations outside the SDWA (e.g., local or State regulations) and could increase the costs of this technology. Consequently, the cost of controlling emissions was estimated as a separate cost item in Table 13 of the July 1990 notice and was included in chapter 7 of the proposed and final T&C document [USEPA, 1992e]. These emission control costs can be added to the PTA costs to get an estimate of the total costs. The costs are based on treatment by vapor-phase GAC.

Empty bed contact time. A number of commenters expressed concern about the use of an empty bed contact time (EBCT) of 7.5 minutes and urged field studies to identify an EBCT or range of EBCT values. A reference cited in the July 1990 proposal on general information about the parameters of the cost model may have misled these commenters. The values used to satisfy the variables of the parameters were stated in the T&C document. The EBCT was used for estimating cost of GAC removal of SOCs in the July 1990 proposal and in today's rule, and the EBCT was assumed to be 10 minutes, not 7.5 minutes. For additional information on the basis for the use of a 10-minute contact time, EPA refers readers to the January 30, 1991 rule [56 FR 3555] and supporting documents.

Carbon usage rate. Some commenters stated that natural organic matter is a major contributor to the carbon use rate (CUR). The concern was that costs of carbon replacement and regeneration would be much higher in actual practice than those calculated in theory. The Agency agrees with these commenters that natural organics contributes to the CUR. To account for the competitive adsorption and fouling of GAC by these organics present in the water matrix, EPA used an adjusted CUR in both the proposed and final rules. The CURs are calculated using an equation derived from the Freundlich isothermal relationship and a mass balance for each specific SOC based on distilled water isotherm data. The CUR is then adjusted by comparison of field to distilled water usage rates to account for the competing effects of natural organics. The method used to determine and adjust the CUR is presented in Chapter 4 of the Technology & Cost Document [USEPA, 1992e] and is a reasonable approximation of the effects of natural organics. The CUR as well as the adjusted CUR provide a mechanism

to compare relative absorbabilities, and ultimately, relative costs. The Agency recommends that each system use its own water quality and geographical conditions, as well as the appropriate EBCT and CURs as part of their design considerations. EPA discussed these same issues in its Phase II final regulation (January 30, 1991 [56 FR 3556]).

Powdered activated carbon as BAT. One commenter suggested that PAC be considered BAT since it can be used for removal of pesticide contamination in surface waters and is the same substance as GAC. EPA's position is that the use of PAC may be an appropriate choice of technology in certain instances. PAC treatment of surface water that is only intermittently contaminated by pesticides or other SOCs could be both economical, in combination with an existing filtration plant, and effective.

While PAC has proven effective in taste and odor control, its efficacy for trace SOC removal in drinking water is variable due to factors such as carbon particle size, background organics, and plant efficiency. Therefore, EPA does not believe that PAC is as effective as GAC overall, and the Agency has not designated it as BAT. If application of PAC will reduce the contaminant below the MCL in particular cases, it may be used in lieu of the designated BAT (for example, if the utility finds that PAC is more cost effective). See discussion above on use of these technologies in lieu of BAT.

BAT for glyphosate. As presented earlier in today's notice, the BAT proposed for glyphosate was GAC. One commenter stated that GAC is not BAT for glyphosate and indicated that conventional treatment is more effective in removing this compound from drinking water. Conventional treatment typically combines disinfection (usually chlorine), coagulation, flocculation, sedimentation, and filtration. EPA agrees that other technologies appear to provide better treatment removal efficiencies for glyphosate than GAC, and conducted additional bench- and pilot-scale studies to evaluate and determine the BAT. As the commenter suggests, and as we determined from subsequent study, GAC is not effective in removing glyphosate from drinking water. Bench-scale treatability studies documented by Speth [Speth, 1990] indicate that oxidation using chlorination (potentially as part of conventional treatment) or ozonation were significantly more effective treatment techniques for glyphosate than is GAC. EPA stated in the

November 1991 NOA [56 FR 60954] that it was considering designating these technologies instead of GAC as BAT for glyphosate. Today, EPA is identifying oxidation (using chlorination or ozonation) instead of GAC as BAT for glyphosate.

The proposed BAT was based on treatment evaluations conducted using distilled water and a limited number of data points. Subsequent bench-scale analyses [Speth, 1990] revealed that glyphosate's behavior in natural waters is unlike that of any of the other SOCs associated with this rulemaking. Glyphosate exhibits very different treatability characteristics in distilled water than in natural waters. This is thought to be due to extremely slow kinetics and the influence of organo/metallic complexation. These additional studies also provided a preliminary examination of the effectiveness of various other treatment methods for removing glyphosate. The results indicated that carbon did not remove glyphosate under raw water conditions, but oxidation, specifically chlorine or ozone, was very effective. These bench-scale studies also seemed to suggest that under some conditions glyphosate could be removed by membranes and coagulation/filtration. These bench scale studies were completed too late for inclusion in the July 1990 proposal. EPA made these bench-scale studies available for public comment in the November 1991 NOA.

During 1991, the Agency conducted pilot-scale studies to further evaluate the effectiveness of conventional treatment (including chlorination and ozonation). The results of the pilot studies demonstrated that lower levels of glyphosate were detected after chlorination or ozonation. The pilot study also showed, however, that conventional treatment, which typically combines disinfection (usually by chlorine), coagulation/flocculation/sedimentation and filtration, has not added effect over chlorination or ozonation. The results of these pilot-scale studies were too late to be included in the November 29, 1991 NOA [56 FR 60954].

One commenter raised a number of concerns in response to the November 1991 NOA regarding the designation of oxidation as BAT for glyphosate. The commenter argues that by selecting chlorination (or oxidation by chlorine) as BAT the oxidation by-products themselves may present health risks and may need to be regulated under the SDWA in the future. The commenter goes on the state that the costs associated with the treatment

modifications that would be required to accommodate an oxidation process could be appreciable. In addition, public water suppliers already have to contend with the Surface Water Treatment Rule (SWTR), disinfection by-product (DBP) concerns, and upcoming DBP regulation. The commenter also states that the bench-scale studies included in the public docket of the NOA [Speth, 1990] indicated that conventional coagulation/flocculation/sedimentation was being overlooked by the Agency, and that additional studies should be conducted, beyond bench-scale, to evaluate the effects of pH, coagulant, water matrix, etc., on the removal of glyphosate by conventional methods.

As mentioned earlier in response to comments, the Agency conducted follow-up pilot studies to evaluate the effectiveness of the various treatment alternatives identified by Speth [Speth, 1990]. While chlorination used as a treatment method could raise concerns of associated health risks due to disinfection by-products (DBPs), these concerns can be addressed through effective precursor removal. This approach is fully consistent with EPA's anticipated approach in the upcoming DBP regulations. To the degree existing disinfection also accomplishes oxidation of glyphosate, little or no cost would be incurred. Installation of new disinfection has been costed and the cost considered acceptable. Further, the option to choose a treatment technology other than the BAT to meet the MCL when necessitated by specific conditions is available (see earlier discussion of selection of technologies other than BAT). Also, consistent with the commenter's recommendation to do additional pilot-scale studies to evaluate conventional treatment, including coagulation/filtration/sedimentation, EPA has now conducted such studies as described above, and based on these studies, EPA has decided not to identify those technologies as BAT.

The BAT for glyphosate is determined to be oxidation. Details of the treatability studies conducted in support of selecting a BAT for glyphosate can be found in the Technology & Cost Document [USEPA, 1992e] for the SOCs.

BAT for Di(2-ethylhexyl)adipate and endothall. As stated earlier in today's notice, proposed BAT for di(2-ethylhexyl)adipate and endothall was GAC and is not being changed by today's notice. One commenter stated that EPA should use treatability study data instead of relying solely on model predictions to select BAT for di(2-ethylhexyl)adipate. The proposed BAT for di(2-ethylhexyl)adipate and

endothall was based on model predictions due to analytical problems encountered during the earlier treatment evaluations. The Agency recently conducted additional treatability studies to provide additional support for the selection of GAC as BAT for these compounds.

The treatability studies for di(2-ethylhexyl)adipate and endothall demonstrate that GAC is as effective in removing these compounds from drinking water as predicted by the model. In addition, the SDWA section 1412(b)(5) states that GAC is feasible for the control of SOCs. Therefore, the BAT for these compounds remains GAC. Details of the treatability studies conducted for di(2-ethylhexyl)adipate and endothall can be found in the Technology & Cost Document for the SOCs [USEPA, 1992E].

BAT for Benzo(a)pyrene. One commenter suggested that PAC should be used to remove PAHs. As indicated in the T&C document, however, PAHs can be removed more effectively using GAC than by other technologies; therefore, the Agency has defined only GAC as BAT for PAHs. However, any other technology that seems better suited to the particular operating conditions of the particular site can be chosen as long as the MCL for the particular SOC is met. See above for a discussion of the use of other technologies in lieu of BAT.

6. Determination of MCLs

EPA proposed MCLs for 24 chemicals based upon an analysis of several factors, including:

(1) The effectiveness of BAT in reducing contaminant levels from influent concentrations to the MCLG.

(2) The feasibility (including costs) of applying BAT. EPA considered the availability of the technology and the costs of installation and operation for large systems.[1]

(3) The performance of available analytical methods as reflected in the PQL for each contaminant. In order to ensure the precision and accuracy of analytical measurement of contaminants at the MCL, the MCL is set at a level no lower than the PQL.

After taking into account the above factors, EPA then considered the risks at the MCL level for the EPA Group A and B carcinogens to determine whether they would be adequately protective of public health. EPA considers a target risk range of 10^{-4} to 10^{-6} to be safe and protective of public health when

calculated by the conservative linear multistage model. The factors EPA used in its analysis are summarized in Table 18 for the Category I and Table 19 for the Category II and III contaminants, respectively.

a. *Inorganic contaminant MCLs.* The MCLs for the inorganic contaminants promulgated today are at the same level as the promulgated MCLG for each contaminant, except for thallium (see Table 1). Also, EPA is deferring action on sulfate, and no sulfate MCL is promulgated today.

The July 1990 notice proposed alternative PQLs or MCLs for antimony and thallium. Alternative PQLs/MCLs of 0.005 mg/l and 0.01 mg/l were proposed for antimony based on multiples of 5 and 10 times the MDL. As discussed above, however, the final PQL for antimony is not being set as a multiple of the MDL but rather is being set at 0.006 mg/l based on new PE data [USEPA, 1991d]. This PQL is equal to the final MCLG for antimony, as discussed in section III-A. The Agency is, therefore, finalizing the MCL at the same level as the promulgated MCLG of 0.006 mg/l for this contaminant.

The Agency proposed alternative MCLGs/MCLs for sulfate of 400 mg/l and 500 mg/l. Today EPA is deferring promulgation of a sulfate MCL because the Agency believes it needs to consider innovative approaches to regulating sulfate. The length of this deferral period will be determined in the course of ongoing litigation with an interested citizen's group concerning EPA's legal deadlines for establishing regulations for drinking water contaminants. Unlike most drinking water pollutants, sulfate appears to be primarily of concern for unacclimated transient populations (as well as for infants).

Because of the high cost of regulating sulfate, its relatively low risk, and its impact primarily on the transient consumer, EPA is deferring the promulgation of the sulfate MCLG and MCL. In the interim, EPA intends to resolve the following issues: (1) Whether further research is needed on how long it takes infants to acclimate to high sulfate-containing water, (2) whether new regulatory approaches need to be established for regulating a contaminant whose health effect is confined largely to transient populations, and (3) whether the Agency should revise its definition of Best Available Technology for small systems (i.e., what should be considered affordable for transient noncommunity water systems).

During this deferral period, the Agency also intends to consider ways to expedite the process for granting potential exemptions and variances to

ease the impact of eventual regulations on small systems. Also in the interim, the Agency plans to issue a Health Advisory and encourage States where sulfate levels may be high to conduct additional monitoring and encourage the use of alternative water supplies where appropriate.

For thallium, alternative PQLs/MCLs of 0.002 mg/l and 0.001 mg/l were proposed in the July 1990 notice based on 5 and 10 times the MDL. As discussed above, however, the final PQL and MCL for thallium is being set today at 0.002 mg/l based on new PE data [USEPA, 1991d]. The MCL for thallium is limited by the sensitivity of available analytical methods (i.e., it is being set at the PQL). The PQL constraint results in an MCL higher than the 0.0005 mg/l MCLG by a factor of 4. However, the Agency has concluded that the promulgated MCL is adequately protective of health because the MCLG includes a large cumulative safety factor of 3,000. Thus, EPA believes that the health risks of exceeding the MCLG up to the MCL are minimal.

EPA has determined that each inorganic contaminant has one or more BATs to reduce contaminant levels to the MCLG, and that the BAT(s) is feasible (as defined by the Act), analytical methodologies are available to ensure accurate and precise measurement for each MCL, and each MCL adequately protects public health. EPA also calculated the household cost for water suppliers to remove IOC contaminants to or below the MCLs, based on the identified BATs. The inorganic contaminants are not expected to occur in the very large water systems and household costs were not estimated for them. In the largest systems where they may occur (25,000-50,000 population), costs were approximately $100/household per year, and would likely be lower for larger systems. EPA believes these costs are reasonable. Also, the national costs associated with the MCLs for these contaminants, as shown in the RIA, are considered reasonable. Also, the national costs associated with the MCLs for these contaminants, as shown in the RIA, are considered reasonable.

B. *Synthetic organic contaminant MCLs—(1) Category I contaminants.* EPA considered the same factors in determining the proposed MCLs for Category I contaminants as for Category II and III contaminants. However, the proposed MCLGs for Category I contaminants are zero, a level that by definition is not "feasible" because no analytical method is capable of determining whether a contaminant

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[1] EPA also evaluates the national costs and costs to smaller systems in its analysis of economic impacts.

level is zero. The lowest level that can be reliably measured is the PQL. EPA calculated PQLs for these contaminants from available analytical performance data, as described above.

In developing MCLs, the Agency attempts to attain a level as close to the MCLG as is feasible. For carcinogens, EPA evaluates the cancer risk at various contaminant levels in order to ensure that the MCL adequately protects public health. The Agency targets a reference cancer risk range of 10^{-4} to 10^{-6} excess individual risk from lifetime exposure using conservative models which are not likely to underestimate the risk. Since the underlying goal of the Safe Drinking Water Act is to protect the public from adverse health effects due to drinking water contaminants, EPA seeks to ensure that the health risks associated with carcinogenic contaminants are not significant.

For most contaminants regulated today, the PQL is identical to that proposed in the July 1990 notice. In the case of dioxin, EPA lowered the PQL based upon a new MDL study using Method 1613 [USEPA, 1990h]. This study identifies an MDL of 5×10^{-9} mg/l, which is exactly twice as low as the MDL of 1×10^{-8} mg/l that EPA identified in the July 1990 proposal. EPA provided this new information through the November 29, 1991 Notice of Availability. Based on the new information, EPA has decided to set the PQL at five times the MDL, or at 3×10^{-8} mg/l.

In the July 25, 1990 proposed regulation for dioxin [55 FR 30416], EPA proposed to set the PQL (and MCL) at five times the MDL, rather than ten times the MDL, because of concerns about the health risk posed at the concentration corresponding to ten times the MDL. EPA recognized that some loss of analytic precision would likely result from this, but believed it was warranted by the additional health protection that would be ensured by the lower MCL. In soliciting public comment on the new dioxin analytic method (1613) and MDL, EPA asked for comment on this same issue, of whether the additional health protection afforded by a lower MCL warranted the likely reduction in analytic precision. Several commenters expressed concern about likely reduction in analytic precision. In using a multiplier of five rather than ten in setting the PQL (based on the new data), estimated lifetime cancer risks would be reduced from 2.5×10^{-4}, to 1.3×10^{-4}. EPA believes this reduction in risk is warranted, because it brings the MCL closer to the 1×10^{-4} target maximum risk that EPA uses for national primary drinking water regulations. Also, as discussed above, EPA believes that the degradation in analytic precisional accuracy is not unreasonable in going from 50 to 30 ppq.

EPA also calculated the annual household costs for large systems to remove the SOC contaminants to or below the MCL using GAC, PTA or oxidation. As Table 18 shows, these costs are estimate to be generally about $20 per household per year for large systems to install and operate any of these technologies. Cost estimates have not changed from the estimates in the proposal. No significant comments on unit treatment costs were submitted. EPA believes these costs are reasonable, as are the associated national costs as shown in the RIA. EPA therefore promulgates the MCLs at the levels listed in Table 18.

Pursuant to SDWA section 1412(b)(10), the effective date for all MCLs promulgated today (except for the MCL for endrin) is 18 months after publication of today's notice (see the beginning of today's notice for the exact date). The effective date for the MCL for endrin is set at 30 days after publication of today's notice. The MCL for endrin promulgated today represents a relaxation of the existing MCL for endrin (from 0.0002 mg/l to 0.002 mg/l). Even though SDWA section 1412(b)(10) calls for the effective date of MCLs to be 18 months after promulgation, EPA interprets this provision not to apply in the case of an existing MCL that is being revised to a higher level, since utilities do not need time to prepare to meet the revised level (they are, in effect, already required to be meeting it).

TABLE 18—MCL ANALYSIS FOR CATEGORY I SYNTHETIC ORGANIC CONTAMINANTS

SOC contaminant	Final MCLG [1] (mg/l)	Final MCL (mg/l)	10^{-4} risk (mg/l)	PQL (mg/l)	Annual household costs [2]		Notes
					GAC	PTA	
Dichloromethane	0	0.005	0.05	0.005		18.00	
Di(2-ethylhexyl)phthalate	0	0.006	0.4	0.006	$20.00		
Hexachlorobenzene	0	0.001	0.002	0.001	20.00		
Benzo(a)pyrene	0	0.0002	0.0002	0.0002	20.00		
2,3,7,8-TCDD	0	3×10^{-8}	2×10^{-8}	3×10^{-8}	20.00		MCL is at 1.3×10^{-4} risk.

[1] EPA policy is that for all Category I carcinogens the MCLG is zero.
[2] For large systems.

(2) *Category II and III contaminants.* For the Category II and III SOC contaminants listed in Table 19, each of the MCLs was proposed equal to its proposed MCLG. Because the MCLGs for di(2-ethylhexyl)adi-pate and simazine have changed from the levels proposed in July 1990, as discussed above, the MCLs have also changed. The MCL for di(2-ethylhexyl)adipate changed from 0.5 to 0.4 mg/l and the MCL for simazine changed from 0.001 to 0.004 mg/l. The MCL for 1,2,4-trichlorobenzene changed from 0.009 to 0.07 mg/l. Both of these changed MCLs are equal to the final MCLGs, which were revised based on a reassessment of the health data as discussed above.

Section 1412 of the SDWA requires EPA to set MCLs as close to the MCLGs as is feasible (taking costs into consideration). EPA believes that it is feasible to set the MCLs at the MCLGs for the Category II and Category III contaminants because (1) the PQL for each contaminant is at or below the level established by the MCLG; (2) BAT can remove each contaminant to a level equal to or below the MCLG; and (3) the annual household cost to install BAT in large systems is reasonable. Final estimated costs are the same as were established for the proposal. EPA believes that these costs are affordable for large systems. EPA also believes the associated national costs, as shown in the RIA, are reasonable. Therefore, EPA promulgates the MCLs for the non-carcinogenic contaminants equal to their MCLGs.

TABLE 19.—MCL ANALYSIS FOR CATEGORY II AND III SYNTHETIC ORGANIC CONTAMINANTS

SOC contaminant	Final MCLG (mg/l)	Final MCL (mg/l)	PQL (mg/l)	Annual household costs using BAT [1]		
				GAC	PTA	OX
Dalapon	0.2	0.2	0.01	$35.00		
Di(2-ethylexyl)adipate	0.4	0.4	0.005	25.00	$17.00	
Dinoseb	0.007	0.007	0.002	20.00		
Diquat	0.02	0.02	0.004	25.00		
Endothall	0.1	0.1	0.09	35.00		
Endrin	0.002	0.002	0.001	20.00		
Glyphosate	0.7	0.7	0.4			$150-9.00
Hexachlorocyclopentadiene	0.05	0.05	0.001	20.00	17.00	
Oxamyl (Vydate)	0.2	0.2	0.05	25.00		
Picloram	0.5	0.5	0.002	35.00		
Simazine	0.004	0.004	0.001	20.00		
1,2,4-Trichlorobenzene	0.07	0.07	0.005	20.00	17.00	
1,1,2-Trichloroethane	0.003	0.005	0.005	25.00	42.00	

[1] For large systems.

C. Compliance Monitoring Requirements

1. Introduction

The proposed compliance monitoring requirements [55 FR 30427] included specific monitoring requirements for inorganic contaminants (IOCs), volatile organic contaminants (VOCs); and non-volatile synthetic organic chemicals (SOCs). EPA proposed that all community and non-transient non-community water systems comply with the monitoring requirements for all contaminants. EPA also requested comment on whether the MCL for sulfate and the associated monitoring requirements should apply to transient, non-community system since this contaminant is associated with acute effects. The compliance monitoring requirements promulgated in today's rule apply to all community and non-transient non-community water systems. The compliance monitoring requirements that EPA is promulgating today are the minimum currently necessary to determine whether a public water supply delivers drinking water that meets the MCLs.

The proposed compliance monitoring requirements for the contaminants in the July 25, 1990 notice were similar to the monitoring requirements proposed in a May 1989 notice [54 FR 22124] for 38 inorganic and synthetic organic contaminants. In the July 1990 proposal [55 FR 30428], EPA explained that the Agency's goal in promulgated compliance monitoring requirements is to standardize the requirements and to synchronize the schedules to minimize overall sample collection and analysis efforts. In keeping to that goal, the Agency further stated in that notice [55 FR 30429] that changes to the monitoring requirements in the final rule to the May 1989 proposal would likely affect the final requirements for the contaminants in today's notice.

EPA promulgated final regulations for the contaminants in the May, 1989 proposed rule on January 30, 1991 and July 1, 1991 [56 FR 3526 and 56 FR 30266, respectively]. In the January 1991 final rule, EPA described a standard monitoring framework that was developed by the Agency based on the proposed monitoring requirements and on the comments received by EPA in response to the May 1989 notice. The final rule, and the November 1991, NOA concerning today's rule, indicated that EPA intends to apply this framework to future requirements for source-related contamination [i.e., inorganics, VOCs, SOCs and radionuclides], as appropriate. The framework and how it applies to today's rule is described in more detail below.

The contaminants in today's rule usually occur at limited frequencies, thereby justifying flexible monitoring requirements. In general, the possible occurrence of these contaminants in drinking water may be predictable to some extent based upon a multiplicity of factors such as geological conditions, use patterns (e.g., pesticides), presence of industrial activity in the area, type of source or historic record. Therefore, EPA believes that States should be allowed the discretion to increase or decrease monitoring based on established criteria and site-specific conditions. As part of today's rule EPA is withdrawing these contaminants from the unregulated contaminant monitoring requirements of § 141.40 since they will now be monitored as regulated contaminants under §§ 141.23 and 141.24.

In developing the compliance monitoring requirements for these contaminants, EPA considered:

(1) The likely source of drinking water contaminants,

(2) The nature of the potential adverse health effects, i.e., chronic versus acute effects,

(3) Differences between ground and surface water systems,

(4) How to collect samples that are representative of consumer exposure,

(5) Sample collection and analysis costs,

(6) The use of historical monitoring data to identify vulnerable systems,

(7) The limited occurrence of some contaminants, and

(8) The need for States to tailor monitoring requirements to system- and area-specific conditions.

EPA monitoring requirements are designed to ensure that compliance with the MCLs is met and to efficiently utilize State and utility resources. EPA's goal in today's rule is to ensure these monitoring requirements are consistent with monitoring requirements promulgated previously by EPA and with known occurrence trends. The monitoring requirements promulgated today focus monitoring in individual public water systems on the contaminants that are likely to occur, an approach that includes:

• Allowing States to reduce monitoring frequencies based upon system vulnerability assessments for the organic chemicals listed in § 141.61 (a) and (c).

• Allowing States to target monitoring to those systems that are vulnerable to a particular contaminant.

• Allowing the use of recent monitoring data in lieu of new data if the system has conducted a monitoring program generally consistent with today's requirements and using reliable analytical methods.

• Encouraging the States to use historical monitoring data meeting specific quality requirements and other

available records to make decisions regarding a system's vulnerability.

• Requiring all systems to conduct repeat monitoring unless they demonstrate through an assessment or other data that they are not vulnerable.

• Designating sampling locations and frequencies that permit simultaneous monitoring for all regulated source-related contaminants, whenever possible.

• Phase-in monitoring requirements based on system size. For systems with 150 or more service connections, monitoring begins in the first compliance period (January 1, 1993 to December 31, 1995). For those systems with less than 150 service connections, monitoring begins in the second compliance period (January 1, 1996 to December 31, 1998).

Although base monitoring requirements for surface and groundwater systems are the same for all contaminants, groundwater systems will qualify more frequently for reduced monitoring and return more quickly to the base monitoring requirements because (1) the sources and mechanisms of contamination for ground and surface water systems are different, (2) the overall quality of surface waters tends to change more rapidly with time than does the quality of ground waters, and (3) seasonal variations tend to affect surface waters more than ground waters. Spatial variations are more important in ground waters than in surface waters since groundwater contamination can be a localized problem confined to one or several wells within a system. Therefore, monitoring frequency is an important factor to determine baseline conditions for surface water systems, while sampling location within the system generally is more important for groundwater systems. Today's monitoring requirements generally require surface water systems to monitor at an increased frequency for longer periods than groundwater systems.

2. Effective Date

In the July 25, 1990 **Federal Register** Notice, EPA proposed to allow an additional 12 months after the effective date of the rule taking final action on the proposal for public water systems to complete the first round of sampling and analysis and to report the results of such monitoring to the States. The effective date of the rules is by statute, 18 months from promulgation. EPA also proposed to allow an additional 12 months after the effective date of the final regulations for the States to complete vulnerability assessments.

Most commenters supported extending the initial monitoring and

reporting period as well as the date to complete vulnerability assessments. They claimed that the 18 months compliance schedule is too rigorous, especially since extensive investigation is required. Some commenters claimed there is a lack of laboratory capacity for conducting analyses using the new analytical methods and a lack of qualified staff as a rationale for extending the first round of monitoring and the reporting of the results of such monitoring to the States. Other commenters cited the impact on State resources to properly notify water systems regarding the new monitoring requirements, develop the necessary guidance and procedures, train staff, to review vulnerability assessments, reduced monitoring decisions, etc., and to be prepared to administratively handle the data generated, as the rationale for allowing States sufficient time to initiate the monitoring requirements. One commenter suggested that small systems be given more time to comply with the requirements because of the cost burden on these systems. Another commenter suggested that the systems should be allowed to submit to the State their own schedule for compliance for State approval.

In the November 29, 1991 NOA, EPA stated that it was considering requiring that monitoring begin during the first compliance period following promulgation. This change would synchronize the monitoring schedule for the 23 contaminants with those promulgated for other SOCs and IOCs in the January 30, 1991 notice. Two commenters supported this change. However, 14 commenters disagreed with the change since they felt it effectively moved monitoring up three years from what was proposed, there would be a lack of time to conduct vulnerability assessments, inadequate time for laboratories to become certified, and increased cost to States and public water systems.

EPA agrees with the commenters that problems may occur in the early stages of implementing the monitoring requirements. These problems are alleviated to some extent, however, by the fact that this rulemaking is adopting the Agency's Standard Monitoring Framework (which EPA originally adopted in the January 30, 1991 rule setting regulations for 33 contaminants), and is adopting a phased approach for initial monitoring. Specifically, the Agency has decided to require that monitoring for the contaminants in today's rule be completed (1) during the first compliance period, as specified in the Standard Monitoring Framework, which begins January 1, 1993 and ends

December 31, 1995 for systems with 150 or more service connections, and (2) during the period beginning January 1, 1996 and ending December 31, 1998 for systems with fewer than 150 connections. In addition, all vulnerability assessment decisions must be completed prior to the calendar year when the initial monitoring must be completed. Laboratories can be granted provisional certification to perform analyses for the contaminants in today's rule during the 1993–1995 compliance period. See the discussion under Laboratory Certification.

EPA believes this phased-in time frame allows adequate time for implementation of the monitoring requirements since for larger systems it provides for more than two additional years after the effective date of today's rule for completion of the first round of sampling and analysis and for small systems it provides three years additional time. This monitoring schedule also coincides with the sampling and analysis schedule for 38 contaminants previously regulated [56 FR 3526 and 56 FR 30266]. By allowing systems with less than 150 service connections to begin initial monitoring in the second compliance period (January 1, 1996 to December 31, 1998), more time is allowed for States, laboratories, and small systems to be fully prepared (i.e., conduct vulnerability assessments, find funding).

EPA believes that the earlier 1993–1995 compliance period for those systems with 150 or more service connections is appropriate, to better protect health. These systems would have been required to begin monitoring for these contaminants under unregulated monitoring requirements of the January 30, 1991 rule. Since many of the previously unregulated contaminants are contaminants being regulated in today's rule, the Agency believes the 1993 monitoring will result in only minor increased monitoring impact. Those individual contaminants moving from "unregulated" to "regulated" status are being deleted from the unregulated contaminant monitoring requirements.

States have the discretion, and may well choose, to require a percentage (e.g., one-third) of the required systems to monitor during each year of the three-year compliance period. States have the option to prioritize monitoring based on system size. EPA has decided not to allow systems to submit their own monitoring schedule for State approval as some commenters suggested. EPA believes States need to control the flow of samples and data to them in order to

ensure orderly implementation and enforcement, within the regulatory requirements and avoid undue administrative burdens and potentially unmanageable enforcement problems.

3. Standard Monitoring Framework

In response to the May 1989 notice covering a different set of contaminants, EPA received extensive comments stating that the proposed monitoring requirements were complex and would lead to confusion and misunderstanding among the public, water utilities, and State personnel. Commenters also cited the lack of coordination among various regulations. Many commenters suggested that EPA simplify, coordinate, and synchronize the proposed regulation with previous regulations. In response to these comments, EPA developed a Standard Monitoring Framework to reduce the complexity of the monitoring requirements, coordinate the requirements among various regulations, and synchronize the monitoring schedules. This framework is discussed extensively in the January 30, 1991 final rulemaking to the May 1989 Notice [56 FR 3560]. The Agency also indicated that this framework will serve as a guide for future source-related monitoring requirements. The framework was developed based on the proposed requirements, the options and requests for comments EPA discussed in the proposal, and the comments received by EPA.

The use of a Standard Monitoring Framework for the contaminants in today's rule was supported by many of the comments received. Commenters cited the efficient use of resources as the major reason to synchronize the monitoring requirements.

EPA believes that using a Standard Monitoring Framework satisfies the comments that recommended reducing the complexity of the requirements, synchronizing monitoring schedules, standardizing regulatory requirements, and giving regulatory flexibility to States and systems to manage monitoring programs. EPA believes these changes will reduce costs by combining monitoring requirements for the contaminants regulated by the January 30, 1991 rule and today's rule (i.e., the presence of multiple contaminants can be evaluated in a single laboratory sample and analysis, or by a single vulnerability assessment) and will promote greater voluntary compliance by simplified and standardized monitoring requirements.

Use of the framework envisions a cooperative effort between EPA and States. The monitoring requirements promulgated today are the minimum federal requirements necessary to ascertain systems' compliance with the MCLs. In some cases, States will increase the monitoring frequencies beyond the federal minimums to address site-specific conditions.

For all contaminants contained in today's rule, minimum (or base) monitoring requirements requirements may be increased or decreased by States based upon prior analytical results and/or the results of a vulnerability assessment. The monitoring requirements outlined today follow to a large extent the requirements proposed on July 25, 1990. In the July 1990 proposal EPA stated as a goal to efficiently utilize State and utility resources and be consistent with monitoring requirements previously promulgated by EPA. EPA believes that today's requirements meet that goal.

a. *Three-, six-, nine-year cycles.* In order to standardize the monitoring schedule for different regulations, EPA has established nine-year compliance cycles. Each nine-year compliance cycle consists of 3 three-year compliance periods. All compliance cycles and periods run on a calendar year basis (i.e., January 1 to December 31). The January 30, 1991 rule established the first nine-year compliance cycle beginning January 1, 1993 and ending December 31, 2001; the second cycle beginning January 1, 2002 and ending December 31, 2010; etc. Within the first nine-year compliance cycle (1993 to 2001), the first compliance period begins January 1, 1993 and ends December 31, 1995; the second begins January 1, 1996 and ends December 31, 1998; and the third begins January 1, 1999 and ends December 31, 2001.

In the January 1991 Notice, EPA required that initial monitoring (which was defined as the first full three-year compliance period beginning 18 months after the promulgation date of a rule) must begin in the first full compliance period after the effective date of the final rule. EPA solicited comments on this issue in the November 29, 1991 NOA and is modifying initial monitoring, as described above. For today's regulation, the effective date is January 17, 1994. The next full three-year compliance period after this effective date begins January 1, 1996. After reviewing comments received, the Agency has decided that systems serving 150 or more service connections must conduct initial monitoring during the January 1, 1993 to December 31, 1996 period and those serving less than 150 service connections must conduct initial monitoring during the January 1, 1996 to December 31, 1998 period. EPA believes the phase-in of monitoring based on system size will increase public health protection to the public by identifying noncompliance earlier for larger systems which serve a large fraction of the population (and which would have been required to monitor these contaminants in any event under the "unregulated contaminant" requirements of the January 1991 rule). At the same time, the phase-in will allow States, small systems, and laboratories more time to effectively implement today's rule for small systems. EPA believes this is an appropriate balancing of the need to identify noncomplying systems through monitoring, and the implementation burden on States and laboratories. This change would synchronize the monitoring schedule for the 23 contaminants in this rule with those promulgated for other SOCs and IOCs in the January 30, 1991 notice.

Under the July 1990 proposal, monitoring for the contaminants in this rulemaking would have been required to be initiated no later than November 1993 (i.e., the effective date of this rulemaking). EPA does not believe that changing the initial monitoring schedule to begin January 1993 instead of November 1993 for systems with 150 or more service connections will significantly affect costs for those systems. Under this schedule, States must establish an enforceable monitoring schedule for each system during the initial three-year compliance period. States have the discretion to schedule systems by size, vulnerability, geographic location, laboratory access, or by other factors. In some cases systems will not need to conduct monitoring until the latter part of the first three-year period, rather than needing to start monitoring immediately as of January 1993 (see discussion of the Standard Monitoring Framework at 56 FR 3560). In addition, EPA believes there will be a decrease in costs due to the effects of synchronizing the monitoring requirements in this rule with those of earlier rules—e.g., there will be a cost savings resulting from a system's ability to evaluate the presence of multiple contaminants with the analysis of a single sample, and to perform vulnerability assessments covering multiple contaminants.

Several commenters believed that States would be unable to develop adequate certified laboratory capacity in order to monitor during the 1993–1995 period. EPA has responded to this concern by encouraging provisional certification of laboratories, as discussed above.

b. *Base monitoring requirements.* In order to standardize the monitoring

requirements. EPA has established base (or minimum) monitoring frequencies for all systems at each sampling point. These base monitoring frequencies apply to all community and non-transient water systems. In cases of detection or non-compliance, EPA has specified increased monitoring frequencies from the base. These increases are explained below. Systems will also be able to decrease monitoring frequencies from the base requirements by obtaining waivers from the State where a State permits such waivers. Decreases from base monitoring requirements through waivers are discussed in general under the section on decreased monitoring and in the discussion of monitoring frequency for each class of contaminants.

In most cases, these increased or decreased frequencies are similar to the frequencies proposed in July 1990. Specific changes are discussed below under each contaminant group.

Inorganic contaminant base requirements are the same as proposed—one sample at each sampling point every three years for groundwater systems and annually for surface water systems. Modification of base requirements for VOCs is discussed below in the section on VOC monitoring frequency.

For the non-volatile synthetic organic compounds (SOCs), EPA proposed that monitoring was not required unless the State determined that the system was vulnerable based upon a State-conducted assessment. EPA requested comment on the appropriate time frame for completing these assessments. If the State determined that a system was vnlerable to these SOCs, systems would be required to monitor on a three- or five-year schedule depending upon system size and whether contaminants were detected.

The July 1990 notice also included an alternative monitoring scheme which would require all CWSs and non-transient, non-community water systems (NCWSs) to monitor for the non-volatile SOCs at specified (base) frequencies. Most comments EPA received opposed a round of initial monitoring by all systems. These commenters cited the lack of occurrence of these contaminants in drinking water and the expense of monitoring. Several commenters questioned the availability of sufficient laboratory capacity.

After reviewing and evaluating the comments on monitoring for the SOCs in the May 1989 Notice, EPA adopted an alternative monitoring approach which requires systems to monitor at specified base frequencies unless the requirements are waived (either reduced or eliminated) by the State. The reasons for this change are given in the January 1991 rule [56 FR 3560]. In summary, the requirement that all systems monitor for these contaminants is more protective of health than were the proposed requirements because systems will be required to monitor if the State does not conduct a vulnerability assessment, or does not approve a vulnerability assessment conducted by the system. The result of this change is that there will always be an enforceable requirement in the absence of a State waiver.

In today's rule EPA is adopting the same monitoring approach for the SOCs. EPA believes that the cost impact of this approach is the same as under the proposed scheme provided a vulnerability assessment is conducted and a waiver is granted.

EPA has combined the above change with the provision that public water systems may conduct their own vulnerability assessments and, at the State's discretion, may obtain a waiver if they are determined not to be vulnerable (see waiver discussion below). EPA has shifted the responsibility to conduct vulnerability assessments from States to systems because the vulnerability assessment is a monitoring activity that historically has been a system responsibility. Each individual system can decide whether to conduct a vulnerability assessment (rather than simply going right to monitoring) based on cost, previous monitoring history, and coordination with other vulnerability type assessments (i.e., sanitary surveys, Wellhead Protection Assessments). In addition, because of States' indicated resource shortfalls, many States might not conduct vulnerability assessments. Though EPA is permitting systems to conduct vulnerability assessments, approval of waivers based on those vulnerability assessments rests with the States. EPA believes the changes outlined above address, in part, the State resource issue and will result in adequate monitoring and enforceable drinking water standards.

Based on limited occurrence data, EPA anticipates that most systems would qualify for a waiver from monitoring for most SOCs in today's rule. In cases where a system is not granted a waiver by the State, it will be required to monitor at the specified base frequency. In sum, for the reasons specified above, all systems will be required to monitor for all SOCs with an opportunity for reduced monitoring based upon a vulnerability assessment.

c. *Volatile Organic Chemicals (VOCs).* In order to standardize the monitoring requirements for all VOCs, EPA promulgated on July 1, 1991 some modifications to the monitoring requirements for the 18 VOCs in two previous rules (July 8, 1987 and January 30, 1991 Federal Register Notices). The comments submitted to EPA during the comment period for the January 1991 notice revealed support for synchronization of the monitoring requirements and schedules. Therefore, the monitoring requirements in today's rule are identical to the requirements for these previously regulated VOCs [56 FR 39267].

d. *Increased monitoring.* In general, today's rule requires monitoring frequencies to increase when a contaminant is measured at a certain concentration. These concentrations are specified in each rule, and vary by class or toxicity of the contaminant. In today's rule, consistent with the monitoring requirements set forth in the January 1991 rule for other inorganic contaminants, VOCs, and SOCs, these "trigger" concentrations are set at (1) the MCLs for the inorganic contaminants; and (2) the analytical detection limits for VOCs and SOCs. The detection limit for each VOC is 0.0005 mg/l. The SOC detection limits are the method detection limits given in Table 14 and § 141.24(i)(18). The rationale for varying the detection limits for increased monitoring is addressed in each section for the contaminant monitoring frequencies below (also see the January 1991 rule, 56 FR 3560–68).

After exceeding the trigger concentration for each contaminant, systems must immediately increase monitoring to quarterly (beginning in the subsequent quarter after detection) to establish a baseline of analytical results. Groundwater systems are required to take a minimum of two samples and surface water systems must take four samples before the State may permit less frequent monitoring. EPA is requiring surface water systems to take a minimum of four samples (rather than the two samples required for groundwater systems) because surface water is generally more variable than ground water and, consequently, additional sampling is required to determine that the system is "reliably and consistently" below the MCL. Today's rule allows a State, after a baseline is established, to reduce the quarterly monitoring frequency if the system is "reliably and consistently" below the MCL. "Reliably and consistently" means that the State has enough confidence that future sampling results will be sufficiently below the MCL to justify reducing the quarterly

monitoring frequency. At a minimum, all individual samples should be below the MCL. Systems with widely varying analytical results or analytical results that are just below the MCL would not meet this criterion. In all cases, the system remains on a quarterly sampling frequency until the State determines that the system is "reliably and consistently" below the MCL. EPA is adopting this approach based on comments received on the May 1989 and July 1990 proposed rules that suggested the EPA allow States to modify the monitoring schedules in those systems which are less than the MCL. EPA believes this approach will result in consistency among the regulatory requirements for the different classes of contaminants.

In the July 1990 proposal, EPA requested comment on whether EPA should reduce the three year quarterly monitoring requirement to one year of quarterly monitoring in situations where initial monitoring shows particularly low levels of detection relative to the levels of concern (i.e., MCLs) or in situations where cleanup activities have resulted in low levels of detection. Several commenters indicated that a minimum of 12 quarters after monitoring had been increased by a trigger level was too long and supported a reduction in the monitoring requirements in cases such as these. These commenters suggested that EPA should require sufficient monitoring to establish a baseline. In the January 1991 Notice EPA prescribed a minimum of two samples for groundwater systems and four samples for surface water systems to establish a baseline. EPA is adopting the same approach today because the Agency agrees with commenters who pointed out that systems whose analytical results remain below the MCL do not pose a health threat.

In the July 1990 proposal, the Agency proposed to reduce the repeat monitoring requirements when a contaminant is consistently detected at less than 50 percent of the MCL. Many commenters objected to this trigger, stating that it was "arbitrary". The Agency modified this requirement in the January 1991 notice with respect to other contaminants to give States additional flexibility to reduce monitoring for those systems whose analytical results are "reliably and consistently less than the MCL" (see §§ 141.23(c)(8), 141.24(f)(11)(ii) and 141.24(h)(7)(ii) 56 FR 3560–68, 3580, 3584, 3586). EPA has decided that systems meeting this criteria are also eligible for reductions from the increased monitoring frequency requirements for the contaminants in today's rule.

e. *Decreased monitoring.* Systems may decrease monitoring from the base requirement by receiving a waiver from the State. State waivers may either eliminate the monitoring requirement for that compliance period (for SOCs) or reduce the frequency (for inorganics and VOCs). Waivers are either based on a review of established criteria ("a waiver by rule") or by a vulnerability assessment.

A "waiver by rule" is based simply on meeting certain criteria set out in EPA regulations and based, for example, on previously collected analytical results. For example, § 141.23(c) (originally adopted in the January 1991 notice and, by this notice, applicable to the contaminants in today's rule) specifies that States may grant "waivers by rule" to systems for five inorganic contaminants. The waivers are effective for up to nine years (or one compliance cycle). In order to qualify for a waiver, a system must have a minimum of three previous samples (including one taken after January 1, 1990) with all analytical results below the MCL. The State must consider a variety of issues in making a "waiver by rule" determination, such as: (1) Reported concentrations from all previous monitoring, (2) degree of variation in reported concentrations, and (3) other factors which may affect contaminant concentrations such as groundwater pumping rates, changes in the system's configuration, changes in the system's operating procedures, or changes in stream flows or characteristics.

A "waiver by vulnerability assessment" may take one of two forms. The first involves a determination as to whether a given contaminant which does not occur naturally is or was used, manufactured, and/or stored in an area nearby the system. If the contaminant is not used, manufactured, and/or stored nearby, the system can receive a "use waiver." Second, if a "use waiver" cannot be granted, a system may conduct a thorough assessment of the water source to determine the system's susceptibility to contamination. Susceptibility considers: (1) Prior analytical and/or vulnerability assessment results, (2) environmetal persistence and transport, (3) how well the source is protected, (4) wellhead protection program reports, and (5) elevated nitrate levels. Systems with no known susceptibility to contamination (based upon an assessment of the above factors) may be granted a "susceptibility waiver."

All waivers must be granted on a contaminant-by-contaminant basis. However, systems and States will find it

economical to apply for and grant the waiver for those contaminants that may be analyzed using the same analytical methods. This packaging of assessments and State decision making will yield significant cost savings to both systems and State primacy programs.

Waivers for the SOCs and VOCs may be granted after the system conducts a vulnerability assessment and the State determines the system is not vulnerable based on that assessment. A waiver must be renewed during each compliance period. Waivers for inorganic contaminants may be granted for up to nine years. If a system does not receive a waiver by the beginning of the year in which it is scheduled to monitor, it must complete the base monitoring requirement.

One change that EPA is adopting in § 142.92 is that EPA may rescind waivers issued by a State where the Agency determines that the State has issued a significant number of inappropriate waivers. EPA does not intend to utilize this provision except in special situations where the State has not followed its own established and EPA-approved protocols and procedures (see also the discussion on State primacy requirements). If a waiver is resinded, the system must monitor in accordance with the base requirements in today's rule.

f. *Vulnerability assessments.* EPA received numerous comments on the issue of vulnerability assessments. In the July 1990 Notice, EPA requested comment on several alternatives for the process of making vulnerability decisions. One option involved requiring States to assess the overall hydrogeological vulnerability of each water source supplying a PWS instead of making contaminant-specific determinations for each contaminant at each PWS. Another option was to assess the overall use of each contaminant within specific regions, focusing on potential sources of contamination within a defined region. EPA also requested comment on whether systems should be required to monitor for all contaminants that are subject to the same analytical technique. EPA proposed to allow States to conduct area-wide assessments (based on contaminant use information) or one assessment of the water source susceptibility to contamination (based on hydrogeological information).

Commenters generally supported the use of vulnerability assessments as a first step in lieu of requiring all systems to monitor. Different opinions were expressed regarding how to conduct these assessments.

Some commenters indicated that EPA should provide detailed guidelines that States would use to make vulnerability determinations. Examples cited included the development of environmental fate documents, identification and characterization of the available sources of information regarding the presence of contaminants, and disposal facilities that may impact water sources, among others. Other commenters questioned whether State agencies would have sufficient financial and human resources to collect the necessary information to conduct an assessment of a water system's vulnerability.

EPA has decided that a detailed protocol for what is usually a very site-specific analysis is not appropriate. Instead, EPA desires that each State develop its own specific vulnerability assessment procedures that use the general guidelines established by EPA. The Agency believes that the States are in the best position to develop detailed protocols. If a State chooses not to develop these procedures, systems cannot receive waivers and must monitor at the base requirements.

In the proposal, EPA listed the following criteria systems must consider in conducting vulnerability assessments for SOCs: Previous analytical results; proximity of the system to sources of contamination; environmental persistence; protection of the water source; and nitrate levels as an indicator of potential contamination by pesticides. For VOCs, the criteria were previous monitoring results, number of people served, proximity to a large system, proximity to commercial or industrial use, storage or disposal of VOCs, and protection of the water source.

EPA received comments on the process of how to make vulnerability decisions. Comments ranged from allowing the use of area-wide assessment to contaminant-specific assessment for individual supplies. One commenter suggested combining two options proposed (assessing the overall hydrological vulnerability of the water supplies and assessing the overall contaminant use). EPA agrees with this comment and, as part of the earlier rulemaking for 38 contaminants, has made several changes to the vulnerability assessment criteria and the process to simplify the procedure [56 FR 3562]. Today's rule also adopts these changes. First, a two-step waiver procedure is available to all systems. Step #1 determines whether the contaminant that does not occur naturally is or was used, manufactured, stored, transported, or disposed of in the area. In the case of some contaminants

an assessment of the contaminant's use in the treatment or distribution of water may also be required. "Area" is defined as the watershed area for a surface water system or the zone of influence for a groundwater system and includes effects in the distribution system.

If the State determines that the contaminant was not used, manufactured, stored, transported, or disposed of in the area, then the system may obtain a "use" waiver. If the State cannot make this determination, a system may not receive a "use" waiver but may receive a "susceptibility" waiver, discussed below. Systems receiving a "use" waiver are not required to continue on to Step #2 to determine susceptibility. EPA anticipates that obtaining a "use" waiver will apply mostly to the SOCs where use can be determined more easily than for VOCs. Obtaining a "use" waiver for the VOCs will be limited because VOCs are used extensively in the United States. If a "use" waiver cannot be given, a system may conduct an assessment to determine susceptibility, Step #2.

Susceptibility considers prior occurrence and/or vulnerability assessment results, environmental persistence and transport of the chemical, the extent of source protection, and Wellhead Protection Program reports. Systems with no known "susceptibility" to contamination based upon an assessment of the above criteria may be granted a waiver by the State. If "susceptibility" cannot be determined, a system is not eligible for a waiver. A system must receive a waiver by the beginning of the calendar year in which it is scheduled to begin monitoring.

Several commenters requested that EPA permit "area wide" or geographical vulnerability assessment determinations. Though EPA at this time is skeptical that "area wide" determinations can be conducted with sufficient specificity to predict contamination over a large area, the final rule allows this option when States submit their procedures for conducting vulnerability assessments to determine "use" waivers.

EPA's goal is to combine vulnerability assessment activities in other drinking water programs with today's requirements to create efficiencies. EPA also desires to use the results of other regulatory program requirements, such as Wellhead Protection Assessments, to determine a system's vulnerability to contamination. Systems and States may schedule today's assessments with sanitary surveys required under the

Total Coliform Rule [54 FR 27546], watershed assessments, and other water quality inspections so that all regulatory, operational, and managerial objectives are met at the same time.

In the July 25, 1990 Notice, EPA solicited comments on whether the contaminant source assessments conducted under State Wellhead Protection Programs (see section 1428 of the SDWA) could be used for the vulnerability assessments and what the relationship of the two assessments should be. Commenters were supportive of this concept but requested that specific guidance be developed to determine how this might be accomplished and where it is appropriate.

EPA intends to issue a guidance that will give flexibility to States in conducting vulnerability assessments and allow them and local public water systems to meet these and similar requirements under the Wellhead Protection Program, satisfying the requirements of both programs with one assessment. Additionally, this combined assessment approach may be used to meet similar requirements under the evolving Underground Injection Control (UIC)—Shallow Injection Well Program.

g. *Relation to the Wellhead Protection (WHP) program.* As stated in the January 1991 Notice, the Agency plans to integrate particular elements of the Public Water System, Wellhead Protection, and UIC programs related to contaminant source assessments around public water supply wells. Specifically, the Agency plans to prepare a guidance document on groundwater contaminant source assessment that merges the vulnerability assessment of the PWS program for SOCs and VOCs with the wellhead delineation and contaminant source which can be used to establish priorities of UIC wells. This integration is expected to assist State and local drinking water program managers responsible for groundwater supplies to more efficiently and effectively administer the portion of their programs addressing source protection and will be the basis for determining monitoring frequency. The guidance will give States flexibility in revising vulnerability/contaminant source assessments.

Section 1428 of the SDWA requires each State to submit a WHP program for EPA review and approval in order to be eligible for grant funds to support the State's wellhead protection efforts. The implementation of WHP programs by States may be phased in to allow resources to be used most effectively. This matter can be addressed in the State WHP submittal.

When States submit WHP programs for approval in the future, program documents should address how the State will phase requirements for Wellhead Protection Areas (WHPAs) with other PWS regulations. In some States, to be most effective, this program integration may need to be accomplished through a coordinating agreement or other mechanism among several State agencies. The guidance would allow States to tailor their program provisions to conditions in the States, within broad guidelines. Information from the other related groundwater programs (such as Superfund, RCRA) will be useful in this assessment. This information also includes identification of sources not regulated under Federal programs, but perhaps regulated by States, such as septic tanks. Therefore, States may be able to meet similar requirements of these three programs through following a general set of guidance procedures.

A State may choose from several methods to delineate WHPAs. As long as the method is determined to be protective, a State may choose a simplified method described in "Guidelines for the Delineation of Wellhead Protection Areas" [USEPA, 1987a]. If a State desires more information for use in the decision-making process, it may choose more sophisticated methods identified in the "Guidelines." EPA has made available to States and local agencies computer software and training for use of the "Guidelines" to make the process of WHPA delineation less difficult.

WHPAs may incorporate recharge areas as long as they are within the jurisdiction of the agencies identified in the EPA-approved programs. However, WHPAs must meet the requirements of this rule if they are to be used to make monitoring waiver determinations. The State cannot accept a WHP program in lieu of a vulnerability assessment if the recharge area is not covered to meet all the requirements of this rule.

Once a WHPA is delineated, a State may desire to apply a range of assessment measures to define hydrogeologic vulnerability within the delineated area. A State may decide on a method of assigning priorities to the public water systems based on vulnerability, size, or other criteria acceptable to EPA.

EPA's Ground-Water Protection Division has developed a document entitled "Managing Ground Water Contamination Sources in Wellhead Protection Areas: A Priority Setting Approach" [USEPA, 1991h] to help States and local water supply managers prioritize potential contaminant sources

in carrying out their programs for resource protection, a concern of one commenter. This system could also be used in setting monitoring priorities but was not designed specifically for that application. The States may use the regulatory mechanisms available to them (e.g., RCRA permits, NPDES permits) to determine the point sources of regulated, and potentially contaminating, substances in or near areas needing protection, such as wellhead and recharge areas.

h. *Ground water policy.* The Agency now has a new, integrated ground-water policy. In July, 1989, EPA established a Ground-Water Task Force to review the Agency's ground-water protection policies. The outcome of this effort is the Ground-Water Task Force Report, which includes EPA's Ground-Water Protection Principles [USEPA, 1991e]. The Principles are intended to foster more effective and consistent decision-making in all Agency decisions affecting ground water.

With respect to prevention, the Principles call for ground water to be protected to ensure that the nation's currently used and reasonable expected drinking water supplies, both public and private, do not present adverse health effects and are preserved for present and future generations. Ground water should also be protected to ensure that ground water that is closely hydrologically connected to surface waters does not interfere with the attainment of surface water quality standards, which are designed to protect the integrity of associated ecosystems. Ground-water protection should be achieved through a variety of means including: pollution prevention programs aimed at eliminating and minimizing the amount of pollution that could potentially affect ground water, source control, siting controls, the designation of wellhead protection areas and future water supply areas, and the protection of aquifer recharge areas. Efforts to protect ground water must consider the use, value, and vulnerability of the resource, as well as social and economic values.

With respect to remediation, the Principles call for activities to be prioritized to minimize human exposure to contamination risks first, and then to restore currently used and reasonably expected sources of drinking water and ground water closely hydrologically connected to surface waters, whenever such restorations are practicable and attainable.

With respect to Federal, State, and local responsibilities, under the Principles, the primary responsibility for developing and implementing

comprehensive ground-water protection programs continues to be vested with the States. An effective ground-water protection program must link Federal, State, and local activities into a coherent and coordinated plan of action. EPA should continue to improve coordination of ground-water protection efforts within the Agency and with other Federal agencies with ground-water responsibilities.

This rule responds to the Ground-Water Protection Principles in the following ways. With respect to the Principles' emphasis on prevention, this rule sets MCLs and monitoring frequencies for 18 synthetic organic and five inorganic chemicals. These MCLs will be used for ground water protection (i.e., as an indication of possible need for source control) as well as surface water protection. The rule also recognizes State wellhead protection areas as a method of prevention and a basis for granting waivers.

With respect to the allocation of Federal, State, and local responsibilities, this rule gives States the authority to grant reductions in monitoring frequency, based on a vulnerability assessment. The guidance document for this rule will give flexibility to the States in conducting vulnerability assessments. As a method of coordination among the PWS, UIC, and Wellhead Protection Programs, the guidance document will allow States to use the methods and approaches of the Wellhead Protection Program in meeting the requirements for vulnerability assessments.

i. *Initial and repeat base monitoring.* Initial monitoring is defined as the first full three-year compliance period that occurs after the regulation is effective. As described in the January 1991 Notice [56 FR 3564], under the standard monitoring framework, States have flexibility to schedule monitoring for each system during the three-year compliance period. As discussed earlier, all systems must monitor at the base monitoring frequency unless a waiver is obtained. The initial monitoring period for today's regulation begins January 1, 1993 and ends December 31, 1995 for public water systems having 150 or more service connections. For systems having less than 150 connections, the initial monitoring period will be from January 1, 1996 through December 31, 1998. After the system fulfills the initial (or first) base monitoring requirement, it must monitor at the repeat base frequency. Generally the repeat base frequency is the same as the initial monitoring frequency but in some instances the base monitoring frequency may be

reduced based on previous analytical results.

Also, under today's rule, EPA is requiring the States to establish a sampling schedule that may result in approximately one-third of the systems monitoring during reach of the three years of a compliance period at the State's discretion. States will have the flexibility to designate which systems must monitor each year based upon criteria such as system size, vulnerability, geographic location, and laboratory access. EPA believes that allowing States the discretion to schedule monitoring for each system during the compliance monitoring period will enable States to manage their drinking water programs more efficiently.

In cases where EPA is the primacy authority for today's regulation (i.e., where the State has not adopted regulations corresponding to the NPDWRs in today's rule by its effective date, and in States and on Indian lands where EPA retains primary enforcement responsibility), systems will be required to complete monitoring within 12 months after notification by EPA. In such cases, EPA intends to use a prioritizing scheme similar to the kind that the States will use. This should minimize the disruption to the regulated community when the State does adopt the requirements and begins to develop its own monitoring schedules for systems within the State.

Once a system is scheduled for the first, second, or third year of a compliance period, the repeat schedule is set for future compliance periods. For example, if a system is scheduled by the State to complete the initial base requirement by the end of the first year, all subsequent repeat base monitoring for that system must be completed by the end of the first year in the appropriate three-year compliance period. This is necessary to prevent systems from monitoring in the first year of the first compliance period and the third year of the repeat base period.

4. Monitoring Frequencies

a. *Inorganics*—(1) *Initial and repeat base requirements*. In the July 1990 Notice, EPA proposed that surface water systems monitor annually and groundwater systems monitor every three years. Some commenters supported that frequency. Other commenters suggested that the Agency should allow waivers based on vulnerability assessments for the initial round of monitoring. The monitoring frequencies in today's rule are identical to these proposed frequencies. EPA disagrees with commenters regarding the issuance of waivers in lieu of an

initial round of monitoring. A reduction in monitoring frequency may be appropriate if the levels found are reliably and consistently below the MCL (see discussion on decreased monitoring below). Systems with 150 or more service connections will be required to take the initial base sample for each inorganic during the initial compliance period of 1993 to 1995 (subject to State scheduling). Surface water systems with 150 or more service connections that are on an annual sampling schedule are required to start in 1993.

(2) *Increased monitoring*. In the January 1991 Notice, EPA added a requirement that systems that exceed the MCL (either in a single sample or with the average of the original and repeat sample) and which, consequently, are out of compliance must immediately (i.e., the next calendar quarter after the sample was taken) begin monitoring quarterly. Systems must continue to monitor quarterly until the primacy agent determines that the system is "reliably and consistently" below the MCL. Groundwater systems must take a minimum of two samples and surface water systems must take a minimum of four samples after the last analytical result above the MCL, before the State can reduce monitoring frequencies back to the base requirement (i.e., annually for surface systems and every three years for groundwater systems).

EPA made this change for several reasons. First, it is consistent with the monitoring requirements contained elsewhere in this rule that more frequent monitoring occur in instances of non-compliance. Second, EPA believes that systems that are out of compliance should, in general, monitor more frequently to determine the extent of the problem. If EPA has not made this change, groundwater systems that exceed the MCL could continue to monitor every three years. EPA believes the previous frequencies for ground and surface systems were not adequate to protect the public in those cases where systems exceeded the MCL.

(3) *Decreased monitoring*. In both the May 1989 and the July 1990 Notices, EPA proposed that systems be allowed to reduce the monitoring frequency to no less frequent than once every 10 years between monitoring episodes provided a system had previously taken three samples that were all less than 50 percent of the MCL. States would base their decision on prior analytical results, variation in analytical results, and system changes such as pumping rates or stream flows/characteristics.

EPA received numerous comments on the 50 percent trigger for reduced monitoring with most commenters

opposing the 50 percent trigger, calling it arbitrary. In the January 1991 notice, EPA decided to eliminate the 50 percent trigger and change the condition for reduced monitoring to require three compliance samples, all of which are "reliably and consistently" less than the MCL, to give the States additional flexibility to decide which systems are eligible for reduced monitoring. Systems meeting this criterion are also eligible for reduced monitoring for the contaminants in today's rule. While States have discretion in making this determination, EPA believes that as a minimum, all individual samples should be below the MCL before the determination should be made.

Most commenters supported the 10-year time frame as a reasonable monitoring frequency for reduced monitoring. Because EPA has adopted a 3/6/9-year compliance cycle, EPA has changed the maximum reduced monitoring frequency from the proposed 10 years to 9 years to gain consistency in its regulations. EPA believes this change will have a minimal impact on systems. EPA is requiring at least one of the three previous samples to be taken since January 1, 1990. The other two samples could be taken at any time after January 1, 1988. Because the reduction in monitoring to every nine years begins in the 1993–2001 compliance cycle, EPA believes that one sample must be recent (i.e., taken after January 1, 1990 for systems scheduled to monitor in 1993) to preclude unduly long time frames occurring between samples. Data obtained to satisfy monitoring requirements for unregulated contaminants specified in the January 1991 notice may be used to reduce the monitoring frequencies. Systems receiving a waiver may monitor at any time during the nine-year compliance cycle, as designated by the State.

b. *Cyanide*. In the July 1990 Notice, EPA proposed monitoring requirements for the IOCs applicable to all community (CWS) and non-transient non-community water systems. Several commenters disagreed with the requirement to monitor for cyanide at non-vulnerable systems. They argued that the main sources of cyanide contamination are industrial and manufacturing processes, not natural occurrence, and that it would be more appropriate to regulate cyanide under the requirements that apply to synthetic organic compounds (SOCs), which distinguish vulnerable and non-vulnerable systems.

The Agency agrees with these commenters and has changed the requirement for cyanide to require only

vulnerable systems to monitor. provided a waiver (by vulnerability assessment) is available and has been granted by the State.

Other commenters stated that the monitoring requirements for all the IOCs in today's notice should apply to vulnerable systems only, and that EPA should allow waivers based on vulnerability assessments for the initial round of monitoring. EPA disagrees with these commenters (except for cyanide because it does not occur naturally at concentrations near the MCL) because some minimum monitoring requirements for the inorganic contaminants will provide a baseline of data on the natural background levels expected for these contaminants. Systems may qualify for reduced monitoring once a baseline of data shows levels that are reliably and consistently below the MCL, thus decreasing the monitoring burden.

c. *Volatile Organic Contaminants (VOCs)*—(1) *Initial and repeat base requirements*. In the rule promulgated in July 1987 setting MCLs for eight VOCs, EPA required all systems to take four consecutive quarterly samples. Groundwater systems that conducted a vulnerability assessment and were judged not vulnerable, however, could stop monitoring after the first sample provided no VOCs were detected in that initial sample. Repeat frequencies for all systems vary by system size, detection, and vulnerability status.

On July 1, 1991, EPA amended the monitoring requirements for VOCs to streamline the requirements and to make all VOC requirements consistent [56 FR 30267]. For the contaminants in today's rule, the July 1990 proposal made distinctions in base requirements for VOCs between ground and surface water systems, less than and more than 500 service connections, and vulnerable and non-vulnerable systems. In today's final rule, to be consistent with the July 1991 rule, and for the reasons discussed there [56 FR 30267], EPA is requiring all groundwater systems as well as surface water systems to initially take four quarterly samples for the VOCs (dichloromethane, 1,2,4-trichlorobenzene, and 1,1,2-trichloroethane), regardless of size or vulnerability status. Systems that do not detect VOCs in the initial round of four quarterly samples are required to monitor annually beginning in the next calendar year after quarterly sampling is completed. For example, systems which complete quarterly monitoring in calendar year 1993 are required to begin annual monitoring in 1994. The State may allow groundwater systems which conducted three years of sampling and

have not detected VOCs to take a single sample every three years thereafter. The reasons for these changes are further explained in the January 1991 notice [56 FR 3566].

In the May 1989 proposal covering 38 contaminants, EPA requested comment on whether vulnerable systems may take only one sample if no VOCs are detected in the initial year of monitoring. EPA's intent was to require quarterly sampling in vulnerable systems, but most commenters opposed a change to more frequent monitoring. Based on the comments received on that notice, EPA specified in the January 1991 final rule for 33 of the 38 contaminants that vulnerable systems will be required to take one annual sample (instead of four quarterly samples) if no VOCs were detected in the initial (or subsequent) monitoring. For consistency, EPA has adopted this same requirement for the VOCs in today's rule.

(2) *Increased monitoring*. In the proposal, systems detecting VOCs (defined as any analytical result greater than 0.0005 mg/1) were required to monitor quarterly. In today's rule, EPA is requiring systems that detect VOCs to monitor quarterly until the State determines that the system is "reliably and consistently" below the MCL. However, groundwater systems must take a minimum of two samples and surface water systems must take a minimum of four samples before the State may reduce the monitoring to the base requirement (i.e., annual sampling).

Systems remain on an annual sampling frequency even if VOCs are detected in subsequent samples, unless an MCL is exceeded (or if the State otherwise specifies). In this case, the system returns to quarterly sampling in the next calendar quarter until the State determines that the new contamination has decreased below the MCL and is expected to remain reliably and consistently below the MCL. This determination shall again require a minimum of four quarterly samples for surface water systems and two quarterly samples for groundwater systems.

EPA has made this change because some systems may detect VOCs at a level slightly above the detection limit. EPA believes that where the State can determine that contamination is "reliably and consistently" less than the MCL, those systems should be able to return to the base monitoring requirement (i.e., annually). Giving States the discretion to determine whether systems meet this criterion may

allow States to give monitoring relief to some systems.

(3) *Decreased monitoring*. States may grant waivers to systems that are not vulnerable and did not detect VOCs while conducting base monitoring. Vulnerability must be determined using the criteria specified above in the discussion of vulnerability assessments. EPA anticipates that most systems will not be able to qualify for a "use" waiver because of the ubiquity of VOCs. However, systems conducting an assessment that considers prior occurrence and vulnerability assessments (including those of surrounding systems), environmental persistence and transport, source protection, Wellhead Protection Assessments, and proximity to sources of contamination may apply to the State for a "susceptibility" waiver. If the waiver is granted, systems are required to take one sample and update the current vulnerability assessment during two consecutive compliance periods (i.e., six years). The vulnerability assessment update must be completed by the beginning of the second compliance period. EPA has increased the time frame from five to six years to bring the five-year monitoring frequency in the proposal in line with the 3/6/9-year frequencies specified in the standard monitoring framework.

States have the discretion to set subsequent frequencies in systems that did not detect VOCs in the initial round of four quarterly samples and that are designated as not vulnerable based on assessment. The repeat monitoring frequency for groundwater systems meeting this criteria shall be not less than one sample every six years as discussed above. For surface water systems meeting this criteria, the repeat frequency is at State discretion.

d. *Synthetic Organic Chemicals (SOCs)*—(1) *Initial and repeat base requirements*. In the proposal, systems were not required to monitor for the non-volatile SOCs unless the State, on the basis of a vulnerability assessment, determined the system to be vulnerable. Once determined vulnerable by the State, a system would be required to take four consecutive quarterly samples. EPA requested comment on an alternative approach that would require all systems to monitor for all contaminants. As discussed below, today's requirements specify that all systems monitor for all SOCs by taking four quarterly samples every three years, unless decreased or increased monitoring requirements apply. All systems are eligible for waivers from the quarterly monitoring requirement, as

discussed in the section on decreased monitoring below.

Most comments on the proposal revolved around two issues—the requirement that systems monitor quarterly and the requirement that all systems monitor at the time of highest vulnerability. Many commenters stated that quarterly monitoring was not necessary to detect changes in contamination. Many commenters recommended annual monitoring for pesticides. After reviewing the information and comments submitted, EPA believes that quarterly monitoring remains the best scheme to determine contamination. Occurrence information available to EPA indicates that seasonal fluctuations from runoff and applications of pesticides may occur; thus, quarterly monitoring is better than annual monitoring to determine pesticide contamination. In some cases, States may consider it appropriate to require monitoring at greater frequencies than those specified by today's rule to better determine exposure. States have the option to require monitoring at greater frequencies than the federal minimums in today's rule. Systems, of course, may always monitor more frequently when they deem it prudent.

Most commenters opposed the requirement to monitor at the time of highest vulnerability, stating the highest vulnerability, stating that highest vulnerability cannot be predicted or determined. Several commenters stated that the requirement to monitor at the time of highest vulnerability was unenforceable. EPA agrees and eliminates this requirement from today's rule. However, States are advised to examine sampling practices of systems to assure that periods of likely contamination are not avoided. This is especially true for surface water systems monitoring for pesticides after rainfall and/or application of pesticides.

EPA proposed that systems conduct repeat monitoring every three or five years, depending on system size and ground/surface distinctions. In today's rule, the repeat monitoring frequency for all systems is set at four consecutive quarterly samples each three-year compliance period, unless decreased or increased monitoring requirements apply. EPA has made several adjustments for systems that do not detect contamination in the initial compliance period. After the initial monitoring round is completed, systems that serve 3,300 or more persons may reduce the sampling frequency to two samples in one year during each compliance period. Systems serving less

than 3,300 persons may reduce the sampling frequency to one sample per compliance period. EPA has increased the frequency at which small systems must monitor in this rule from every five years to every three years, because EPA believes that this change will offer greater health protection. EPA believes that every five years is too long an interval to determine changes in consumer exposure.

EPA has made the granting of "use" waivers for pesticides easier in this rule by permitting States to grant "area wide" or "Statewide" waivers based upon pesticide use information. EPA anticipates that many systems will be able to obtain a "use" waiver. Therefore, the impact of the increased monitoring frequency discussed in the above paragraph should be minimal. For those systems not able to obtain a waiver (i.e., vulnerable systems), EPA believes it is appropriate to monitor at three-year intervals to determine contamination.

(2) *Increased monitoring.* EPA proposed that systems with 500 or less service connections that detect SOCs contamination monitor annually, while systems with more than 500 service connections that detect SOCs would monitor quarterly. EPA defined detection as greater than 50 percent of the MCL. Many comments revolved around the 50 percent trigger. Consistent with the above discussion concerning VOCs, EPA is redefining detection for SOCs to mean the method detection limit (as specified in the approved analytical method). EPA believes it is appropriate to use the method detection limit as the trigger for increased monitoring because detection implies that the potential for increasing contamination exists. Consequently, additional monitoring is required to determine the extent and variability of SOCs contamination. In today's rule, all systems that detect SOCs must comply with the baseline monitoring requirements (i.e., waivers are not available).

As described in the proposal, upon detection, all systems must immediately begin quarterly monitoring. The State may reduce the requirements to annual monitoring for SOCs after determining that samples are "reliably and consistently" below the MCL. A reduction to annual monitoring may occur after a minimum of two samples for groundwater and four samples for surface water systems. After three years of annual monitoring which remains "reliably and consistently" below the MCL, systems can return to the base monitoring requirement for SOCs (i.e.,

four quarterly samples every three years).

(3) *Decreased monitoring.* Systems that obtain a waiver from the monitoring requirements are not required to monitor. All systems are eligible for waivers in the first three-year compliance period of 1993 to 1995. As discussed above, EPA has simplified the vulnerability assessment procedures by allowing the system to assess whether the contaminant has been used, transported, mixed, or stored in the watershed or zone of influence. Where previous SOCs use in the area can be ruled out, systems may apply to the State for a use waiver. EPA's intent in promulgating this change is to make it easier for systems to obtain waivers in those situations where the chemical has not been used. States may be able to determine that the entire State or specific geographic areas of the State have not used the contaminant and consequently grant "area wide" waivers. Systems that cannot determine use may still qualify for a waiver by evaluating susceptibility according to the criteria discussed in the VOC section above. Waivers must be renewed every three years.

e. *Sulfates.* Some commenters believed that systems violating the sulfate MCL should not be required to monitor quarterly, because sulfate levels are stable, and additional monitoring would provide no new information. EPA has collected additional data on sulfate levels and agrees with the comment. However, as discussed above, EPA is not setting a final MCL for sulfate today and is, therefore, not setting final monitoring requirements for sulfate. For the time being, monitoring for sulfate will continue to be required under the provisions for monitoring of unregulated contaminants established in the January 1991 rulemaking.

5. Other Issues

a. *Compliance determinations.* One commenter opposed the use of a single sample to determine compliance with the IOC MCLs for systems that monitor yearly or less frequently. The commenter argued that this procedure provides an advantage to the system required to monitor quarterly, because if an annual average is the basis for compliance an entire year may go by before the system monitoring quarterly is deemed out of compliance and public notification is required, whereas the system monitoring annually is deemed out of compliance immediately if it violates the MCL once. The commenter recommended that all systems monitor

on a quarterly basis with compliance based on a running average.

EPA believes that quarterly monitoring is not generally necessary for the IOCs and is no longer requiring initial quarterly monitoring. However, if the system exceeds the MCL at any sampling point, then the system is out of compliance (based on the original and one confirmation sample, at State discretion) and quarterly monitoring is thereafter required. For those systems monitoring more frequently than annually, the Agency requires that if any one sample would cause the annual average to be exceeded, then the system is out of compliance immediately and public notification is required. In addition, a system, if it wishes, may apply to the State to conduct more frequent monitoring of the IOCs than the minimum frequencies specified in this regulation (see § 141.23(h)). Under § 141.23(i), systems that are monitoring at a greater than annual frequency determine their compliance by a running annual average of results.

EPA believes that this approach puts emphasis on monitoring on those systems that are of greatest concern while providing cost savings to most systems.

b. *Confirmation samples.* Several commenters stated that collection of a confirmation sample within 14 days of the original sample is unrealistic. EPA continues to believe that the 14-day period is reasonable for the collection of a confirmation sample since it is important to get a conclusive determination of any MCL exceedance as soon as possible. In addition, one commenter stated that confirmation of negative samples should not be required due to cost constraints. In response, the collection of confirmation samples is not a federal requirement, but a State option. The Agency agrees that States should consider costs in making decisions about confirmation samples, especially for negative results.

c. *Compositing.* EPA proposed to allow systems, at the discretion of the State, to composite up to five samples. Compositing must be done in the laboratory. Some commenters supported compositing as a methodology to cut costs. In this final rule, EPA is limiting compositing among different systems to only those systems serving fewer than 3,300 people. Systems serving greater than 3,300 persons will be allowed to composite but only within their own system. EPA also requested comments on whether State discretion on compositing is necessary or whether systems can composite automatically without State approval. Several States opposed this change; consequently, the final rule is unchanged from the proposal. EPA believes that compositing is to be used only when cost savings are important and systems alone should not make that determination. Today's rule limits compositing to those contaminants where the MDL is less than one-fifth of the MCL, in order to avoid situations where compositing of five samples would mask the presence of a contaminant in one sample by dilution with the other samples.

d. *Polynuclear Aromatic Hydrocarbons (PAHs).* In the July 1990 proposal, EPA requested comments on the following monitoring issues related to the PAHs: (1) Should fluoranthene and naphthalene be used as indicators of the potential presence of carcinogenic PAHs; (2) should EPA require sampling at the tap; and (3) should PAH monitoring be at State discretion if the State bans the use of coal tar in distribution systems. Below is a summary of the comments on these issues and EPA's response.

Use of indicators: Commenters generally opposed the use of non-regulated PAHs such as naphthalene and fluoranthene to determine a system's vulnerability to PAH contamination and recommended that systems monitor only for BaP (and any other PAHs the Agency decides to regulate). For the reasons stated earlier in today's notice, EPA is promulgating an MCLG and an MCL for BaP only at this time. On reconsideration, EPA agrees that naphthalene and fluoranthene are not necessarily good indicators for the presence of BaP in water. On reconsideration of the data, EPA acknowledges that BaP is much less soluble than naphthalene and fluoranthene, and has not been found to co-occur with them. Therefore, EPA has decided against the use of these PAHs as indicators of BaP contamination in drinking water. This is consistent with the commenters' recommendations.

Sampling at the tap: EPA received numerous comments on this issue. Most commenters opposed sampling at the tap, claiming that it is neither acceptable nor appropriate to sample at the tap for PAHs. These commenters argued that coal tar, which may be a major source of PAH contamination in the distribution system, is not used in home plumbing and that the tap is a location beyond the control of the water utility. Some commenters suggested, however, that sampling in the distribution system, downstream of the lined section of the system, may be appropriate. One commenter further stated that monitoring for PAHs originating from the distribution system should be a "one-time effort" under worst case conditions.

Elsewhere in today's rulemaking, EPA has explained that it is regulating only BaP within the group of PAHs. MCLs have not been set for other PAHs that the proposal indicated EPA was considering regulating.

Further, there are data indicating that BaP does not leach from materials in the water delivery system (i.e., distribution system pipe materials, storage tanks), as noted by one commenter. Survey of data on leaching of BaP from U.S. water storage/distribution systems has revealed that data are available for at least 36 U.S. cities. In these studies water samples were collected from the treatment site as well as from one or more locations in the storage and/or distribution system. The increase in concentration of BaP from distribution systems in these studies has ranged from none to 2.9 ppt [Saxena et al., 1978; Robeck, 1978; Zoldak, 1978; McClanahan, 1978; Alben, 1980; Basu et al., 1987]. Laboratory studies involving exposure of tap water to panels coated with coal tar coating support these findings [Alben, 1980; Lampo, 1980]. Higher BaP concentration (78–110 ppt) in the water was reported only in one laboratory study where rigorous leaching conditions not representing actual distribution/storage system exposure were used [Sorrell et al., 1980]. In addition, coal tar and asphaltic linings are not generally used in home plumbing which is usually copper, galvanized, or plastic piping.

Based on these studies, EPA has concluded that contribution of BaP from coal tar-lined storage and distribution systems is very small overall and is only a small percentage of the final BaP MCL. Therefore, EPA has decided that there is no need to set controls for BaP contributions from the materials in the water delivery system. This contaminant is appropriately controlled by controlling its levels in source water, as is true for the other contaminants in today's rule. Consequently, EPA has determined that there is no need for today's rule to require monitoring at the tap or anywhere else in the distribution system.

Coal tar ban/States' discretion for monitoring. Commenters generally opposed banning the use of coal tar and asphaltic linings in the distribution system and storage tanks at this time. One commenter suggested that additional evaluation of the potential risks due to the use of coal tar linings in water distribution systems is necessary before recommending discontinuation of their use. Another commenter stated

that the banning of the use of coal tar may not be warranted, especially in light of the ubiquitousness of PAHs in foodstuffs and consumer products. One commenter indicated that its water supplier had halted the further use of coal tar materials in the late 1970s. This commenter indicated it has found cost-effective alternatives for both pipes and tanks.

As noted above, the Agency finds that the contribution of BaP from coal tar lined pipes and storage tanks is generally very small relative to dietary sources, as one commenter stated. It is possible, however, that there may be leaching of PAHs other than BaP due to coal tar in the distribution system. Thus, the Agency believes that States should carefully evaluate any actions related to this potential source of contamination (such as banning the further use of coal tar) to be sure that action is warranted.

With respect to State discretion concerning monitoring requirements if it bans the use of coal tar, one commenter stated that vulnerable systems should still be required to monitor, while another commenter indicated that monitoring should be at State discretion, and a third commenter recommended that monitoring at the tap be at State discretion. EPA has carefully considered these comments and is not requiring that systems monitor for BaP in the distribution system, as discussed above.

D. Variances and Exemptions

1. Variances

Under section 1415(a)(1)(A) of the SDWA, EPA or a State that has primacy may grant variances from MCLs to those public water systems that cannot comply with the MCLs because of characteristics of their water sources. At the time a variance is granted, the State must prescribe a compliance schedule and may require the system to implement additional control measures. The SDWA requires that variances may only be granted to those systems that have installed BAT (as identified by EPA). However, in limited situations a system may receive a variance if it demonstrates that the BAT would only achieve a *de minimis* reduction in contamination (see § 142.62(d)). Before EPA or a State issues a variance, it must find that the variance will not result in an unreasonable risk to health.

Under section 1413(a)(4) of the Act, States with primacy that choose to issue variances must do so under conditions and in a manner that is no less stringent than EPA allows under section 1415. Before a State may issue a variance, it must find that there were no opportunities for the system to (1) join

another water system, or (2) develop another source of water and thus comply fully with all applicable drinking water regulations.

The Act permits EPA to vary the BAT established under section 1415 from that established under section 1412 based on a number of findings such as system size, physical conditions related to engineering feasibility, and the cost of compliance. Paragraph 142.62 of this rule lists the BAT that EPA has specified under section 1415 of the Act for the purposes of issuing variances. This list mirrors the proposed list except that oxidation (chlorination or ozonation) is considered BAT for glyphosate, as discussed in "Selection of Best Available Technology" above. Tables 20 and 21 provide a list of the section 1415 BATs for the inorganic and organic compounds in this rule.

TABLE 20.—SECTION 1415 BAT FOR INORGANIC COMPOUNDS

Chemical	BATs
Antimony	2,7
Beryllium	2,5,6,7
Cyanide	5,7,10
Nickel	5,6,7
Thallium	5,7

Key to BATs in Table 2:
2 = Coagulation/Filtration (not BAT for systems with <500 service connections).
5 = Ion Exchange.
6 = Lime Softening (not BAT for systems with <500 service connections).
7 = Reverse Osmosis.
10 = Chlorine.
11 = Ultraviolet.

TABLE 21.—SECTION 1415 BAT FOR ORGANIC COMPOUNDS

Chemical	PTA [1]	GAC [2]	OX [3]
Benzo(a)pyrene		X	
Dalapon		X	
Dichloromethane	X		
Di(2-ethylhexyl)adipate	X	X	
di(2-ethylhexyl)phthalate		X	
Dinoseb		X	
Diquat		X	
Endothall		X	
Endrin		X	
Glyphosate			X
Hexachlorobenzene		X	
Hexachlorocyclo-pentadiene	X	X	
Oxamyl (Vydate)		X	
Picloram		X	
Simazine		X	
1,2,4-Trichlorobenzene	X	X	
1,1,2-Trichloroethane	X	X	
2,3,7,8-TCDD (Dioxin)		X	

[1] PTA = Packed tower aeration.
[2] GAC = Granular activated carbon.
[3] OX = Oxidation (Chlorination or Ozonation).

2. Exemptions

Under section 1416(a), a State or EPA may grant an exemption extending

deadlines for compliance with a treatment technique or MCL if it finds that (1) due to compelling factors (which may include economic factors), the PWS is unable to comply with the requirement; (2) the exemption will not result in an unreasonable risk to human health; and (3) the system was in operation on the effective date of the NPDWR, or, for a system not in operation on that date, no reasonable alternative source of drinking water is available to the new system.

In determining whether to grant an exemption, EPA expects the State to determine whether the facility could be consolidated with another system or whether an alternative source could be developed. It is possible that very small systems may not be able to consolidate or find a low-cost treatment. EPA anticipates that States may wish to consider granting an exemption when the requisite treatment is not affordable.

Under section 1416(b)(2)(B) of the Act, an exemption may be extended or renewed (in the cases of systems that serve 500 or less service connections and that need financial assistance for the necessary improvements) for one or more two-year periods provided that no unreasonable risk to the health of persons would result from granting the exemption.

3. Point-of-Use Devices, Bottled Waters and Point-of-Entry Devices

Under sections 1415(a) and 1416(b) of the SDWA, when the State grants a variance or exemption, it must prescribe an implementation schedule and any additional control measures that the system must take. States may require the use of point-of-use (POU) devices, bottled water, point-of-entry (POE) devices and other mitigating devices as "additional" control measures if an "unreasonable risk to health" would otherwise exist. Sections 142.57 and 142.62 allow these measures as an interim control measure while a variance or exemption is in effect.

4. Public Comments

EPA received several comments regarding the issuance of variances and exemptions. Comments were concerned about the high cost of the proposed BAT technologies (reverse osmosis and ion exchange) for sulfate for small systems that may need to obtain variances under section 1415 of the SDWA. One commenter states that variances and exemptions are temporary and that systems will still be required to comply at some point. This commenter further states that any cost saving due to granting of temporary variances or

exemptions must be reduced by the costs of complying with the "interim control measures" required under the Act and the transaction costs of documenting and applying for exempt status.

Another commenter argued that health protection is not ensured because systems may be granted variances and exemptions due to the prohibitive cost to implement available technology to achieve lower sulfate levels. This commenter recommended the use of a monitoring program and public notification for sulfates instead of an MCL.

Two commenters stated that EPA should allow States the discretion to grant variances from the sulfate MCL for all systems (large as well as small), as long as the variance does not result in an unreasonable risk to health. These commenters recommend that concerns about the water supply and availability should be considered to be pertinent "characteristics of raw water sources" and that provision of public information and alternate water supplies for sensitive populations could be regarded to be appropriate BATs for granting variances.

EPA Response: In response to the commenters concerned about the high costs of reverse osmosis and ion exchange for sulfate removal, the Agency agrees that these costs are high for very small systems. A majority of the systems which would have been affected had EPA not deferred the sulfate rule serve 500 or less persons. Exemptions for these systems could have been renewed as long as the system qualifies for an exemption under section 1416(b) of the SDWA. The costs given in the Regulatory Impact Analysis (RIA) for regulating sulfate assumed no variances and exemptions are granted (i.e., that all systems treat). Thus, the Agency believes that costs to meet a sulfate regulation would have been lower than those projected in the RIA, after consideration of costs associated with granting variances and exemptions.

In response to the commenter that alleged lack of health protection because variances and exemptions will be granted, a variance or exemption can only be granted if it will not result in an unreasonable risk to health. In addition, the associated public notification requirements whenever an MCL exceedance occurs would have provided additional protection to consumers.

In response to the commenters that recommended allowing the States discretion to grant variances to all systems regardless of size, States do have the discretion to grant variances to all public water systems that cannot

comply with the MCLs because of characteristics of their source waters. Variances generally can only be granted if the systems have installed BAT and have failed to meet the MCL. In granting variances, the State may prescribe interim control measures such as public information or provision of alternate water supplies (e.g., bottled water).

The population served by transient water systems is likely to be at greatest risk of suffering from the adverse effects of sulfate. Because populations that regularly consume water containing sulfate will acclimate to its effects, it is people using higher sulfate water on a transient basis that make up the population at risk. This group is largely travelers, i.e., visitors to communities or facilities that are non-transient non-community public water systems, or visitors to facilities such as gas stations, campgrounds or other recreational facilities that serve an almost exclusively transient population. It is this latter group of facilities or public water systems that are most likely to serve water to non-acclimated persons who are at risk from high sulfate.

Sulfate's high treatment cost, low risk, and impact primarily on the transient consumer, combine to create a different set of regulatory challenges than posed by most other drinking water contaminants. For these reasons, EPA is deferring the sulfate standard for a current undetermined period. Specifically, EPA is seeking to extend the legal deadline for establishing the sulfate standard for a period that would allow the Agency to resolve the following issues: (1) Whether further research is needed on how long it takes infants to acclimate to high sulfate-containing water, (2) whether new regulatory approaches need to be established for regulating a contaminant whose health effect is confined largely to transient populations, and (3) whether the Agency should revise its definition of Best Available Technology for small systems (i.e., what should be considered affordable for transient noncommunity water systems). During this deferral period, the Agency also intends to consider ways to expedite the process for granting potential exemptions and variances to ease the impact of these regulations on small systems. Also in the interim, EPA plans to issue a Health Advisory for sulfate and to encourage States where sulfate levels may be high to conduct additional monitoring and encourage the use of alternative water supplies where appropriate.

E. Public Notice Requirements

1. General Comments

Two comments were received on the general issue of public notification requirements. One commenter stated that the required public notifications should provide a more accurate and balanced explanation of potential health effects. The second commenter stated that public notification should not be required unless contaminant levels remain excessive after BAT has been installed.

EPA Response: EPA believes that the public notification language prescribed is, and should be, simple and non-technical in nature while providing sufficient information to the public about the health implications. EPA believes that the statements are accurate and balanced. The Agency also believes that the public has the right to know whenever there is a violation of a standard. The public water system may supplement the notice with additional information such as the steps being taken to meet the standards as long as the notice informs the public of the health risks which EPA has associated with violation of the standards and the mandatory health effects language remains intact.

2. Contaminant-Specific Comments

Two commenters provided specific suggestions on changes for the public notification language for several contaminants. These changes were editorial in nature.

EPA Response: EPA has made most of the changes suggested, as appropriate.

F. Secondary MCL for Hexachlorocyclopentadiene

EPA proposed a secondary maximum contaminant level (SMCL) based upon odor detection levels for hexachlorocyclopentadiene (HEX). Odor detection for this organic chemical has been reported at levels lower than the MCL of 0.05 mg/l. The July 1990 notice proposed to set the SMCL for this compound at 0.008 mg/l.

EPA received two comments on the proposed SMCL for HEX. One commenter stated that an SMCL for HEX will "erode the public's confidence in the overall quality of the drinking water," and recommended against an SMCL for this compound. Another commenter opposed the proposed SMCL alleging it is based on an inadequate experimental basis. The commenter argued that the literature citation [Amoore and Hautala, 1983] was based on theoretical extrapolation (from air odor thresholds), and the levels have not

been confirmed by any published literature.

After reviewing the public comments, EPA has decided to defer promulgating an SMCL for HEX. EPA disagrees with the first comment and believes that taste and odor problems do have an adverse impact on consumers' confidence in the drinking water supply. However, the Agency agrees with the second commenter that additional work is necessary to determine appropriate levels for aesthetic effects. Accordingly, the Agency may initiate in the future a "National Task Force of Experts" to review and assess the data, information and opinions available with respect to taste and odor problems in public water supplies [as noted at 56 FR 3572, January 30, 1991].

G. State Implementation

The Safe Drinking Water Act provides that States may assume primary implementation and enforcement responsibilities. Fifty-five out of 57 jurisdictions have applied for and received primary enforcement responsibility (primacy) under the Act. To implement the federal regulations for drinking water contaminants, States must adopt their own regulations which are at least as stringent as the federal regulations. States must also comply on the requirements in 40 CFR 142.12 on revising approved primacy programs. This section of today's rule describes the regulations and other procedures and policies States must adopt or have in place to implement the new regulations.

To implement today's rule, States will be required to adopt the following regulatory requirements when they are promulgated: § 141.23, Inorganic Chemical Sampling and Analytical Requirements; § 141.24, Organic Chemicals Other Than Total Trihalomethanes, Sampling and Analytical Requirements; § 141.32, Public Notice Requirements (i.e., mandatory health effects language to be included in public notification or violations); § 141.61 (a) and (c), Maximum Contaminant Levels for Inorganic and Organic Chemicals.

In addition to adopting drinking water regulations no less stringent than the federal regulations listed above, EPA is requiring that States adopt certain requirements related to this regulation in order to have their program revision application approved by EPA. In various respects, the NPDWRs provide flexibility to the State with regard to implementation of the monitoring requirements under this rule. Because State determinations regarding vulnerability and monitoring frequency

will have a substantial impact with implementation of this regulation, today's rule requires States to submit, as part of their State program submissions, their policies and procedures in these areas. This requirement will serve to inform the regulated community of State requirements and also help EPA in its oversight of State programs. These requirements are discussed below under the section on special primacy requirements.

1. Special State Primacy Requirements

To ensure that the State program includes all the elements necessary for an effective and enforceable program, the State's request for approval must contain a plan to ensure that each system monitor for the contaminants listed in this rule by the end of each compliance period.

In general, commenters supported the proposed primacy requirements. Most of the comments were very similar to those made on a previous proposed rulemaking (May 22, 1989, [54 FR 22135]), including the following: The States do not have enough resources, States should not have to report vulnerability assessments to EPA, and records should be kept for less than the 40-year requirement. These issues were all addressed in the January 1991 rule [56 FR 3574].

Numerous comments were made regarding requirements for sulfates. One commenter was concerned about the cost impacts on small systems trying to achieve compliance with the proposed MCL options of 400 mg/l and 500 mg/l. Under the SDWA, exemptions may be granted by a State which would have helped alleviate the cost impact of compliance for sulfate. Another commenter claimed that if variances and exemptions were allowed for sulfates, a significant portion of the population would not be protected. Under sections 1415 and 1416, before a State may grant a variance or exemption it must determine that the variance or exemption will not result in an unreasonable risk to health. In addition, a State must notify the public and provide an opportunity for a public hearing before a variance or exemption is granted. Also, the State may require that bottled water, POU devices, or POE devices be used as a condition for granting the variance or exemption. In this manner, EPA believes that public health would have been protected where variances and exemptions were granted for sulfate. To comply with today's rule, States may update their monitoring plan submitted under the January 1991 rule or they may simply note in their application that they will use the same

monitoring plan for this group of contaminants.

In general, States may use their discretion to schedule when, within the overall three-year compliance period, each system will need to perform its one-year-long initial monitoring. For example, States may decide to schedule approximately one-third of the systems for monitoring during each of the three years, to provide for an even flow of samples through State-certified laboratories. States will be able to establish their own criteria to schedule the systems to monitor but the schedules must be enforceable under State law.

If a State does not have primacy for today's rule at the time the initial compliance period begins (i.e., January 1, 1993), then EPA will be the primacy agent. Because water systems must monitor, EPA has established procedures (§§ 141.23(k), 141.24(f)(23), and 141.24(h)(18)) that require systems to monitor at the time designated by the State. If EPA implements today's provisions because a State has not yet adopted the regulatory requirements in today's rule, EPA intends to use the State's monitoring schedule to schedule systems during each compliance period. EPA believes this approach will reduce confusion over the required monitoring schedule that might occur upon the eventual transfer of primacy from EPA to the State.

2. State Recordkeeping Requirements

Some commenters characterized the proposed recordkeeping requirements as burdensome and unwarranted. Similar comments were received in reference to the May 1989 proposed rules [54 FR 22135]. Similar comments were received in reference to the May 1989 proposed rules. In response to comments received on that proposal, EPA modified the State recordkeeping requirements to alleviate the State burden. These changes are explained in the January 1991 rule at 56 FR 3575. No additional changes have been made in today's rule to the recordkeeping requirements.

3. State Reporting Requirements

Generally, commenters characterized the proposed State reporting requirements as burdensome and useless. Similar comments were received in response to the May 1989 proposed regulations [54 FR 22136]. In finalizing those regulations, EPA deleted the proposed reporting requirements (except for unregulated contaminants), having determined that the core reporting requirements of the Primacy Rule (December 20, 1989 [54 FR 52126]) would be sufficient (see 56 FR 3576).

Today's rule similarly deletes the proposed reporting requirements and relies on the core reporting requirements of the Primacy Rule.

IV. Economic Analysis

In accordance with Executive Order 12291, the Environmental Protection Agency (EPA) has performed a Regulatory Impact Analysis (RIA) which is required for all "major" regulations. A rule is considered "major" if it is expected to cause:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

An economic analysis, titled Economic Impact Analysis of Proposed National Primary Drinking Water Standards for 24 Inorganic and Synthetic Organic Chemicals (Revised Final) April 1990, was prepared [USEPA, 1990c]. An addendum to the EIA, dated May 15, 1990, reclassified the rule as a "major" rule [USEPA, 1990a]. The EIA indicated that national costs may exceed $100 million if stringent options were exercised. If stringent options were not employed, then costs may not exceed $100 million and the rule may be classified as minor. Another addendum to the EIA which revised the waste disposal costs for sulfate was added to the public docket on August 3, 1990.

Today's final rule is accompanied by a Regulatory Impact Analysis, titled the Regulatory Impact Analysis of Proposed Phase V Synthetic Organic and Inorganic Chemical Regulations [USEPA, 1992d]. However, with the deferral of the sulfate portion of the rule, total costs are projected substantially below those shown in the Regulatory Impact Analysis. The Regulatory Impact Analysis contains sulfate costs because the document was completed before the decision to defer sulfate was made.

In order to estimate the economic impacts these analyses used the following data, where available, for each of the 23 contaminants:

• Occurrence data, to determine the number of systems violating MCLs;

• Treatment and waste disposal cost data and corresponding probabilities that systems will select each of the various treatment and disposal options, to estimate the system level and aggregate costs of achieving the proposed MCLs; and

• Monitoring costs, to estimate aggregate costs of the monitoring requirements.

Occurrence data adequate to estimate the number of systems likely to violate the MCLs are available for 15 of these 23 contaminants. For the remaining 87 contaminants (endothall, diquat, di(2-ethylhexyl) phthalate, glyphosate, hexachlorobenzene, hexachlorocyclopentadiene, 1,1,2-trichloroethane, and 2,3,7,8-TCDD) cost impacts could not be evaluated because national occurrence data are not available. In response to public comments, impacts of the rule are not based on extrapolation from other SOC contaminant occurrence, as in the proposal.

The EIA supporting the proposed rule estimated treatment costs for SOCs to be $11 million per year and also estimated the rule would affect 900 systems. Treatment costs for IOCs varied depending upon the MCL used for sulfate. Treatment costs for IOCs, estimated in the EIA dated April 1990 and modified by the Addendum dated August 3, 1990, were projected to be $60 million and to affect 1,397 systems with a sulfate MCL of 400 mg/1. An estimated 795 systems were projected to spend about $28 million per year to achieve compliance with a sulfate MCL of 500 mg/1. Monitoring costs for the proposed rule, detailed in the Information Collection Request for: Proposed National Primary Drinking Water Regulations For Phase V SOCs and IOCs [USEPA, 1989a], were estimated to be about $6 million per year. Thus, the total annualized cost of the proposed regulations were estimated to be $87 million per year with an MCL of 400 mg/1, and $50 million per year at an MCL of 500 mg/1.

With the receipt of new data or information, EPA made several changes to the proposed economic analysis which would have resulted in an overall increase in the projected compliance costs for the final rule if sulfate has not been deferred. In addition, revised unit cost and occurrence data were incorporated into the final RIA. These changes, and their corresponding effects on the original cost estimates, are described below.

A. Costs of the Final Rule

Treatment and waste disposal costs associated with the final rule are estimated based on occurrence information available for 15 of 23 contaminants in this regulation. For the other 8 contaminants costs were not estimated because adequate occurrence data are not available. Monitoring and State implementation cost estimates include a consideration of all 23 contaminants.

Annualized total water treatment and waste disposal costs are estimated at $31 million per year (Table 22). Monitoring costs are estimated to be about $5 million per year. The annual cost to State drinking water programs to implement the final rule is estimated to be $10 million. Thus, the total annualized compliance cost to the nation is estimated to be $46 million per year. Further, given the uncertainty associated with the inputs used to estimate costs for the 16 contaminants for which occurrence data are available, the total annual cost of this rule could range from approximately $1 million to $128 million. These cost estimates would increase if the 8 contaminants for which costs have not currently been estimated were included.

Of the 23 contaminants covered by this rulemaking, endrin is the only contaminant regulated by an existing National Primary Drinking Water Regulation. The final MCL for endrin promulgated today is greater than the previously existing MCL. No systems are projected to fail the final MCL for endrin. Therefore, no incremental costs of meeting the new MCL are anticipated. However, costs associated with regulating the other 22 contaminants in this rulemaking do represent an increased cost burden.

Table 23 shows the benefits of today's rule. Most contaminants are being regulated on the basis of non-carcinogenic effects. Five contaminants are being regulated on the basis of their carcinogenicity. These are: dichloromethane, benzo(a)pyrene, di(2-ethylhexyl)phthalate, hexachlorobenzene, and 2,3,7,8-TCDD. Insufficient occurrence data were available to estimate the number of cancer cases avoided for these contaminants. For the regulated contaminants that are not carcinogens, the adverse effects associated with exposure are discussed in both the proposed rules and these final rules, under the portions of the preamble that describe derivation of the MCLGs. The benefits of reduced exposure to these contaminants relates to reducing the possibility that water consumers may experience these adverse effects. For example, antimony caused shortened life spans, weight loss, increased cholesterol levels, and reduced blood glucose levels in test animals. The possibility of any of these effects occurring in exposed populations would be reduced by reducing antimony exposure to below the MCL.

TABLE 22.—SUMMARY OF COST ESTIMATES FOR FINAL RULE

	Best estimate	Low estimate	High estimate
Number of Systems Affected	256	30	795
Cost in millions of Dollars			
Capital Water Treatment and Waste Disposal	238	2	925
Operation and Maintenance	14	<1	65
Annualized Cost @3%	30	1	128
Monitoring Costs	5	N/A	N/A
State Implementation Costs	10	N/A	N/A4
Annual cost: Total	46	1	128

TABLE 23.—SUMMARY OF BENEFITS ESTIMATES FOR FINAL RULE

	Best estimate	Low estimate	High estimate
Benefits ($ Millions):			
Population with Reduced Exposure (thousands)	340	4	1,729
Cancer Deaths Avoided	[1] 0.0	N/A	N/A

[1] Of the five carcinogenic contaminants regulated in this package, occurrence data are only available for dichloromethane, and these data indicate that MCL exceedences are unlikely. The estimate here does not include the other 4 carcinogens, nor does it reflect the fact that other contaminants in this package are group "C" possible human carcinogens, but are not being regulated on the basis of carcinogenicity.

B. Comparison to Proposed Rule

The costs and benefits of today's final rule are compared to those estimated for the proposal (Table 24). The differences in the cost estimates are attributable to a variety of changes in the rule and in the available input data used in the analysis. Among the more important changes are the following.

1. Monitoring Requirements

The Agency has developed a standardized monitoring framework (SMF) to address the issues of complexity, coordination of monitoring requirements between various regulations, and synchronization of monitoring schedules. The monitoring requirements in today's rule are somewhat different from those included in the proposed rule, resulting in reduction in annual national monitoring costs of approximately $1 million, for all contaminants, excluding sulfates. The estimated monitoring cost of the final rule is $5 million annually.

In this regulation, EPA is requiring that initial monitoring begin in the first compliance period after the promulgation date for systems having 150 or more service connections. The initial monitoring period for these systems is from January 1, 1993 through December 31, 1995. For systems with fewer than 150 service connections, initial monitoring is from January 1, 1996 to December 31, 1998. All systems must monitor at the base monitoring frequency unless a waiver is obtained. Systems may decrease monitoring from the base requirement upon receiving a waiver from the state. In cases of detection or noncompliance, EPA has specified increased monitoring frequencies.

2. Changes in MCLs

Several MCLs in the final rule have changed from those that were proposed. As discussed above, regulation of sulfate has been deferred and no final MCL has been set. The MCL for di(2-ethylhexyl)adipate is more stringent based on a new health study which

resulted in a revised reference dose. The MCL for 2,3,7,8-TCDD changed from 5×10^{-8} mg/l to 3×10^{-8} mg/l because of recently available analytic chemistry data and the MCL for di(2-ethylhexyl)phthalate changed from 0.004 mg/l to 0.006 mg/l based on reevaluation of the chemistry data. The MCL for beryllium was revised from 0.001 mg/l to 0.004 mg/l based on public comments and because there are inadequate data to justify the more stringent proposal. The MCL for 1,2,4-trichlorobenzene was revised because EPA agrees with public comments that the oral RfD should not be based on an inhalation study, particularly because insufficient pharmacokinetic data are available for route-to-route extrapolation, changing from 0.009 mg/l to 0.07 mg/l. The MCL for antimony was revised based on a reassessment of the relative source contribution, and simazine was revised based on new health effects data which allowed elimination of an uncertainty factor included to account for a data gap.

TABLE 24.—COMPARISON OF COSTS FOR PROPOSED AND FINAL RULES

[Dollar Figures in Millions]

Contaminants	Proposed		Final	
	Systems affected	Total cost (annualized) $ millions	Systems affected	Total cost (annualized) $ millions
Sulfate (400 mg/l)	1,087	67	N/A	N/A
Sulfate (500 mg/l)	485	30	N/A	N/A
IOCs (Excluding Sulfate)	310	3	207	30
SOCs (including pesticides and VOCs	900	11	49	1
Annualized treatment costs	2,297	81	256	31
Monitoring costs	78,703	6	78,703	5
State Implementation costs	54 States and Territories.	Not estimated	54 States and Territories.	10

TABLE 24.—COMPARISON OF COSTS FOR PROPOSED AND FINAL RULES—Continued

[Dollar Figures in Millions]

Contaminants	Proposed		Final	
	Systems affected	Total cost (annualized) $ millions	Systems affected	Total cost (annualized) $ millions
National annualized cost ($M/Yr)		87		46

Note: Totals may not tally due to independent rounding. MCLs of 400 mg/l and 500 mg/l were proposed for sulfate.

3. Changes in Occurrence Data

Some occurrence data used in the final RIA have been changed. A re-evaluation of the National Inorganics and Radionuclides Survey data resulted in revised antimony occurrence estimates and estimates of systems exceeding the MCL. The number of systems estimated to exceed the beryllium MCL changed as a result of MCL changes. Further review of the EPA occurrence document resulted in a revised occurrence estimate for dichloromethane. For di(2-ethylhexyl)adipate, the occurrence estimate has been changed to reflect a re-evaluation of available occurrence data and a change in the MCL. For 8 contaminants (endothall, diquat, di(2-ethylhexyl) phthalate, glyphosate, hexachlorobenzene, hexachlorocyclopentadiene, 1,1,2-trichloroethane, and 2,3,7,8-TCDD) adequate data are not available. In the EIA accompanying the proposed rule,

approximately 82 systems were assumed to fail the MCL for each contaminant and to be required to install treatment equipment. EPA currently believes that there are inadequate data with which to estimate number of systems exceeding the MCLs for these contaminants and that an estimate of 82 systems for each contaminant is potentially inaccurate. While EPA is unable to estimate the number of systems potentially exceeding the MCL it is recognized that an unknown number of systems may be required to install treatment for each contaminant.

4. Changes in Unit Treatment Cost Estimates

The differences between unit treatment costs in today's rule and in the proposed rule are due to differences in the treatment alternatives included, the assumed percentage of production flow treated, and the discount rate used

in annualizing capital costs. Capital costs in the proposed rule were annualized over 20 years at a 10% interest rate to derive annual costs. The 3% interest rate used in today's final rule was selected in order to make the costs of the Phase V regulations comparable to cost estimates prepared for earlier rules.

C. Cost to Systems

Table 25 indicates that relatively few water systems and consumers will be affected by the regulations. However, costs will vary depending upon the specific chemical contaminant and the size of the public water system.

Systems serving 500 or less people will incur higher per household costs because they do not benefit from engineering economies of scale. Households served by these systems would have to pay significantly more, should their system have contamination greater than the MCL.

TABLE 25.—INCREASED COST OF COMPLIANCE IN SELECTED SYSTEM SIZE CATEGORIES

System Size	25–100			101–500			3,301–10,000			25,001–50,000		
Contaminant	Annual Cost per Household	Cost per System	Number of Systems	Annual Cost per Household	Cost per System	Number of Systems	Annual Cost per Household	Cost per System	Number of Systems	Annual Cost per Household	Cost per System	Number of Systems
Antimony	$3,651	$49,500	89	$1,721	$102,800	57	$274	$521,000	10	$137	$1,935,000	2
Nickel	1,747	25,000	4	717	43,300	3	0	0	0	0	0	0
Dichloromethane	353	4,400	18	138	7,300	11	12	25,000	2	0	0	0
Dinoseb	984	12,500	4	343	20,000	3	0	0	0	0	0	0

Note: For systems serving over 1,000,000 people, no MCL exceedance or cost is estimated.

D. Cost to State Programs

In 1988, EPA and the Association of State Drinking Water Administrators (ASDWA) conducted a survey of State primacy program resource needs for implementing the 1986 SDWA amendments. State implementation costs for the Phase V rule were not included in the ASDWA survey. State implementation costs of previously regulated Phase II inorganic and synthetic organic chemicals are estimated to be $21 million during the initial phase. An additional $17 million is estimated to be required for States to

annually conduct enforcement actions, assist in the expansion of laboratory capabilities, and manage compliance schedules. Laboratory expansion undertaken to implement Phase II regulations will largely satisfy the monitoring needs of this rule. Total State implementation costs are anticipated to be in the range of $7 million to $12 million. A gross point estimate of $10 million per year has been selected for today's final rule.

V. Other Requirements

A. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires EPA to consider the effect of regulations on small entities [5 U.S.C. 602 et seq.]. If there is a significant economic effect on a substantial number of small entities, the Agency must prepare a Regulatory Flexibility Analysis (RFA) describing significant alternatives that would minimize the impact. The Agency had determined that the proposed rule, if promulgated would not have a significant economic impact

on a substantial number of small entities.

According to EPA guidelines for conducting RFA assessments, less than 20 percent of a regulated population is not considered a substantial number. The RFA for the final rule indicates that of 77,910 community and non-transient non-community water supplies serving 50,000 or fewer people, about 253 (<1 percent) are estimated to exceed the final MCLs promulgated in today's rule. Therefore, today's rule does not affect a substantial number of such small systems.

Compliance costs for the 253 systems serving 50,000 or fewer people required to install treatment are about $31 million per year for capital and operational maintenance. This is less than one percent of the total national operating expense for such systems. Therefore, at a national aggregate level, the Phase V rule would not have a significant impact on small systems. This finding does not change if the costs of monitoring to these systems, $6 million per year, are included.

The Agency's determination of no significant economic impact on a substantial number of small systems would remain unchanged under a more stringent definition of small systems. Defining systems serving 3,300 or fewer people as small, today's rule would affect 235 of the 65,766 public systems in this size category. This represents less than one percent of such systems. Costs would increase $16 million, or approximately one percent of the total operating expense for all systems in this category. The inclusion of monitoring costs of less than $4 million for such systems does not alter this finding.

EPA's determination of no significant economic impact on a substantial number of small systems would likely also remain the same if occurrence data on the eight contaminants not currently included in this analysis became available. While it is not possible to estimate the number of systems exceeding the MCLS for these contaminants the number is potentially small as these contaminants have rarely been found in drinking water.

Although there will not be a significant economic impact on a substantial number of small systems on the whole, a small number of individual systems may find their costs increasing sharply, depending on the specific contaminant in their water. For example, it can be seen from Table 25 that a system serving 25–100 people with antimony-contaminated water is expected to incur additional annual costs of $49,500. EPA is concerned about such systems. Under the Safe Drinking

Water Act, small systems may obtain an exemption for national primary drinking water regulation requirements if they can demonstrate that the granting of the exemption would not result in an unreasonable risk to health, among other conditions. Other aspects of the regulatory scheme that serve to reduce impacts on small systems are described in the proposal (55 FR 30436) and earlier in this notice.

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). These requirements are not effective until OMB approves them and a technical amendment to that effect is published in the Federal Register.

Public reporting burden for this collection of information is estimated to average 0.6 hours per response for public water systems and 13.6 hours for States to compile each response. These estimates include time for reviewing instructions, searching existing data sources, gathering the information needed, and completing and reviewing the collection of information as well as start-up activities such as staff training. Comments regarding the burden estimate of any other aspect of this collection of information, including suggestions for reducing this burden, should be sent to Chief, Information Policy Branch, PM-223Y, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

C. Federalism Review

Executive Order 12612 requires all federal agencies to consider legislative and regulatory proposals and other major policy actions to determine if they have substantial effects on federalism goals and principles as set forth in the Executive Order. According to EPA's Guidelines for Implementing Executive Order 12612: Federalism, "[i]f an EPA action is mandated or the necessary means to carry it out are implied by statute, then no further federalism assessment is required." Twenty-two of the 23 contaminants regulated today are included in the list of 83 contaminants for which EPA is required to promulgate National Primary Drinking Water Standards. Therefore, a federalism assessment is not required to support this rule for these listed contaminants.

For hexachlorobenzene, which is not on the list of 83 contaminants, a federalism assessment is not required because today's regulation will not have a substantial direct effect on States, the relationship between the Federal Government and the States or on the distribution of power and responsibilities among the various levels of government.

VI. References

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40 CFR Part 136, Appendix B

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List of Subjects in 40 CFR Parts 141 and 142.

Administrative practice and procedure, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting, recordkeeping requirements, Water supply.

Dated: May 18, 1992.

F. Henry Habicht II,

Administrator.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4 and 300j–9.

2. Section 141.2 is amended by revising the definition for "Initial compliance period" to read as follows:

§ 141.2 Definitions.

* * * * *

Initial compliance period means the first full three-year compliance period which begins at least 18 months after promulgation, except for contaminants listed at 141.61(a) (19)–(21), (c)(19)–(33), and 141.62(b) (11)–(16), initial compliance period means the first full three-year compliance period after promulgation for systems with 150 or more service connections (January 1993–

December 1995), and first full three-year compliance period after the effective date of the regulation (January 1996–December 1998) for systems having fewer than 150 service connections.

* * * * *

3. Section 141.6 is amended by adding paragraph (h), to read as follows:

§ 141.6 Effective Date.

* * * * *

(h) Regulations for the analytic methods listed at § 141.23(k)(4) for measuring antimony, beryllium, cyanide, nickel, and thallium are effective August 17, 1992. Regulations for the analytic methods listed at § 141(f)(16) for dichloromethane, 1,2,4-trichlorobenzene, and 1,1,2-trichloroethane are effective August 17, 1992. Regulations for the analytic methods listed at § 141.24(h)(12) for measuring dalapon, dinoseb, diquat, endothall, endrin, glyphosate, oxamyl, picloram, simazine, benzo(a)pyrene, di(2-ethylhexyl)adipate, di(2-ethylhexyl)phthalate, hexachlorobenzene, hexachlorocyclopentadiene, and 2,3,7,8-TCDD are effective August 17, 1992. The revision to § 141.12(a) promulgated on July 17, 1992 is effective on August 17, 1992.

4. Section 141.12 is amended by removing and reserving paragraph (a) in the table to read as follows:

§ 141.12 Maximum contaminant levels for organic chemicals.

* * * * *

(a) [Reserved]

* * * * *

5. Section 141.23, which will be effective, is amended by revising the introductory text to paragraph (a)(4), by revising the introductory text to a (a)(4)(i), (a)(4)(i) table, by adding paragraph (a)(4)(iii), by revising paragraph (c) introductory text, (c)(1), and (i)(1), by redesignating (k)(5) as (k)(6) and revising it, redesignating (k)(4) as (k)(5) and revising it, and by adding a new (k)(4) to read as follows:

§ 141.23 Inorganic chemical sampling and analytical requirements.

* * * * *

(a) * * *

(4) The State may reduce the total number of samples which must be analyzed by allowing the use of compositing. Composite samples from a maximum of five samples are allowed, provided that the detection limit of the method used for analysis is less than one-fifth of the MCL. Compositing of samples must be done in the laboratory.

(i) If the concentration in the composite sample is greater than or equal to one-fifth of the MCL of any inorganic chemical, then a follow-up sample must be taken within 14 days at each sampling point included in the composite. These samples must be analyzed for the contaminants which exceeded one-fifth of the MCL in the composite sample. Detection limits for each analytical method and MCLs for each inorganic contaminant are the following:

DETECTION LIMITS FOR INORGANIC CONTAMINANTS

Contaminant	MCL (mg/l)	Methodology	Detection limit (mg/l)
Antimony	0.006	Atomic Absorption; Furnace	0.003
			0.0008 [6]
		ICP-Mass Spectrometry	0.0004
		Hydride-Atomic Absorption	0.001
Asbestos	7 MFL [2]	Transmission Electron Microscopy	0.01 MFL
Barium	2	Atomic Absorption; furnace technique	0.002
		Atomic Absorption; direct aspiration	0.1
		Inductively Coupled Plasma	0.002
			(0.001) [4]
Beryllium	0.004	Atomic Absorption; Furnace	0.0002
		xl	0.00002 [6]
		Inductively Coupled Plasma [3]	0.0003
		ICP-Mass Spectrometry	0.0003
Cadmium	0.005	Atomic Absorption; furnace technique	0.0001
		Inductively Coupled Plasma	0.001 [4]
Chromium	0.1	Atomic Absorption; furnace technique	0.001
		Inductively Coupled Plasma	0.007
			(0.001) [4]
Cyanide	0.2	Distillation, Spectrophotometric [4]	0.02
		Distillation, Automated, Spectrophotometric [4]	0.005
		Distillation, Selective Electrode [4]	0.05
		Distillation, Amenable, Spectrophotometric [5]	0.02
Mercury	0.002	Manual Cold Vapor Technique	0.0002
		Automated Cold Vapor Technique	0.0002
Nickel	0.1	Atomic Absorption; Furnace	0.001
			0.0006 [6]
		Inductively Coupled Plasma [3]	0.005
		ICP-Mass Spectrometry	0.0005

DETECTION LIMITS FOR INORGANIC CONTAMINANTS—Continued

Contaminant	MCL (mg/l)	Methodology	Detection limit (mg/l)
Nitrate	10 (as N)	Manual Cadmium Reduction	0.01
		Automated Hydrazine Reduction	0.01
		Automated Cadmium Reduction	0.05
		Ion Selective Electrode	1
Nitrite	1 (as N)	Ion Chromatography	0.01
		Spectrophotometric	0.01
		Automated Cadmium Reduction	0.05
		Manual Cadmium Reduction	0.01
Selenium	0.05	Ion Chromatography	0.004
		Atomic Absorption; furnace	0.002
Thallium	0.002	Atomic Absorption; gaseous hydride	0.002
		Atomic Absorption; Furnace	0.001
			0.0007 [6]
		ICP-Mass Spectrometry	0.0003

[1] Using concentration technique in Appendix A to EPA Method 200.7.
[2] MFL = million fibers per liter > 10 μm.
[3] Using a 2X preconcentration step as noted in Method 200.7. Lower MDLs may be achieved when using a 4X preconcentration.
[4] Screening method for total cyanides
[5] Measures "free" cyanides.
[6] Lower MDLs are reported using stabilized temperature graphite furnace atomic absorption.

*   *   *   *   *

(iii) If duplicates of the original sample taken from each sampling point used in the composite are available, the system may use these instead of resampling. The duplicates must be analyzed and the results reported to the State within 14 days of collection.

*   *   *   *   *

(c) The frequency of monitoring conducted to determine compliance with the maximum contaminant levels in § 141.62 for antimony, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium and thallium shall be as follows:

(1) Groundwater systems shall take one sample at each sampling point once every three years. Surface water systems (or combined surface/ground) shall take one sample annually at each sampling point.

*   *   *   *   *

(i) * * *

(1) For systems which are conducting monitoring at a frequency greater than annual, compliance with the maximum contaminant levels for antimony, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium and thallium is determined by a running annual average

at any sampling point. If the average at any sampling point is greater than the MCL, then the system is out of compliance. If any one sample would cause the annual average to be exceeded, then the system is out of compliance immediately. Any sample below the method detection limit shall be calculated at zero for the purpose of determining the annual average.

*   *   *   *   *

(k) Inorganic analysis

(4) Analysis for the listed inorganic contaminants shall be conducted using the following methods:

Contaminant	Methodology	EPA [1,5,12]	ASTM [2]	SM [3]	USGS [4]	Other
Antimony	Atomic Absorption; Furnace [6]	[1] 204.2		3113		
	Atomic Absorption; Platform [6]	[5] 220.9				
	ICP-Mass Spectrometry [6]	[5] 200.8				
	Hydride-Atomic Absorption [9]		D-3697-87			
Asbestos	Transmission Electron Microscopy	[1,2] EPA				
Barium	Atomic Absorption; Furnace [6]	[1] 208.2		3113B		
	Atomic Absorption; Direct [6]	[1] 208.1		3111D		
	Inductively Coupled Plasma [6]	[5] 200.7		3120		
Beryllium	Atomic Absorption; Furnace [6]	[1] 210.2	D-3645-84B	3113		
	Atomic Absorption; Platform [6]	[5] 200.9				
	Inductively Coupled Plasma [6]	[5] 200.7		3120		
	ICP-Mass Spectrometry [6]	[5] 200.8				
Cadmium	Atomic Absorption; Furnace [6]	[1] 213.2		3113B		
	Inductively Coupled Plasma [6]	[5] 200.7				
Chromium	Atomic Absorption; Furnace [6]	[1] 218.2		3113B		
	Inductively Coupled Plasma [6]	[5] 200.7		3120		
Cyanide	Distillation, Spec.	[1] 335.2	D-2036-89A	4500-CN-D	I330085	
	Distillation, Automated, Spec.	[1] 335.3		4500-CN-E		
	Distillation, Selective Electrode		D-2036-89A	4500-CN-F		
	Distillation, Amenable, Spec.	[1] 335.1	D-2036-89B	4500-CN-G		
Mercury	Manual Cold Vapor Technique [9]	[1] 245.1	D3223-86	3112B		
	Automated Cold Vapor Technique [9]	[1] 245.2				
Nickel	Atomic Absorption; Furnace [6]	[1] 249.2		3113		
	Atomic Absorption; Platform [6]	[5] 200.9				
	Atomic Absorption; Direct [6]	[1] 249.1		3111B		
	Inductively Coupled Plasma [6]	[5] 200.7		3120		
	ICP-Mass Spectrometry [6]	[5] 200.8				
Nitrate	Manual Cadmium Reduction	[1] 353.3	D3867-90	4500-NO₃-E		
	Automated Hydrazine Reduction	[1] 353.1				
	Automated Cadmium Reduction	[1] 353.2	D3867-90	4500-NO₃-F		

Contaminant	Methodogy	EPA [1,5,12]	ASTM [2]	SM [3]	USGS [4]	Other
Nitrite	Ion Selective Electrode					WeWWG/ 5880 [7]
	Ion Chromatography	[11] 300.0				B-1011 [8]
	Spectophometric	[1] 354.1				
	Automated Cadmium Reduction	[1] 353.2	D3867-90	4500-NO$_3$-F		
	Manual Cadmium Reduction	[1] 353.3	D3867-90	4500-NO$_3$-E		
Selenium	Ion Chromatography	[11] 300.0				B-1011 [8]
	Hydride-Atomic Absorption [9]		D3859-84A	3114B		
Thallium	Atomic Absorption; Furnace [5,10]		D3859-88	3113B		
	Atomic Absorption; Furnace [6]	[1] 270.2		3113		
	Atomic Absorption; Platform [6]	[1] 279.2				
	ICP-Mass Spectrometry [6]	[5] 200.9				
		[5] 200.8				

[1] "Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring Systems Laboratory, Cincinnati, OH 45268 March 1983. EPA-600/4-79-020.

[2] Annual Book of ASTM Standards, Vols. 11.01 and 11.02, 1991, American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

[3] "Standard Methods for the Examination of Water and Wastewater," 17th edition, American Public Health Association, American Water Works Association, Water Pollution Control Federation, 1989.

[4] Techniques of Water Resources Investigations of the U.S. Geological Survey, "Methods for Determination of Inorganic Substances in Water and Fluvial Sediments," Book 5, Chapter A-1, Third Edition, 1989. Available at Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

[5] "Methods for the Determination of Metals in Environmental Samples." Available at NTIS, PB 91-231498.

[6] Samples that contain less than 1 NTU (nephelometric turbidity unit) and are properly preserved (conc HNO$_3$ to pH <2) may be analyzed directly (without digestion) for total metals, otherwise, digestion is required. Turbidity must be measured on the preserved samples just prior to the initiation of metal analysis. When digestion is required, the total recoverable technique as defined in the method must be used.

[7] "Orion Guide to Water and Wastewater Analysis." Form WeWWG/5880, p. 5, 1985. Orion Research, Inc., Cambridge, MA.

[8] "Waters Test Method for Determination of Nitrite/Nitrate in Water Using Single Column Ion Chromatography. Method B-1011, Millipore Corporation, Waters Chromatography Division, 34 Maple Street, Milford, MA 01757.

[9] For the gaseous hydride determinations of antimony and selenium and for the determination of mercury by the cold vapor techniques, the proper digestion technique as defined in the method must be followed to ensure the element is in the proper state for analyses.

[10] Add 2 ml of 30% H$_2$O$_2$ and an appropriate concentration of matrix modifier Ni(NO$_3$)+6H$_2$0 (nickel nitrate) to samples.

[11] "Method 300. Determination of Inorganic Anions in Water by Ion Chromatography." Inorganic Chemistry Branch, Environmental Monitoring Systems Laboratory. August 1991.

[12] "Analytical Method For Determination of Asbestos Fibers in Water," EPA-600/4-83-043, September 1983, U.S. EPA Environmental Research Laboratory, Athens, GA 30613.

(5) Sample collection for antimony, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium, and thallium under this section shall be conducted using the sample preservation, container, and maximum holding time procedures specified in the table below:

Contaminant	Preservative [1]	Container [2]	Time [3]
Antimony	Conc HNO$_3$ to pH <2	P or G	6 months.
Asbestos	Cool, 4°C	P or G	
Barium	Conc HNO$_3$ to pH <2	P or G	6 months.
Beryllium	Conc HNO$_3$ to pH <2	P or G	6 months.
Cadmium	Conc HNO$_3$ to pH <2	P or G	6 months.
Chromium	Conc HNO$_3$ to pH <2	P or G	6 months
Cyanide	Cool, 4°C, NAOH to pH >12$_4$	P or G	14 days
Fluoride	None	P or G	1 month
Mercury	Conc HNO$_3$ to pH <2	P or G	28 days.
Nickel	Conc HNO$_3$ to pH <2	P or G	6 months
Nitrate			
Chlorinated	Cool, 4°C	P or G	28 days.
Non-chlorinated	Conc H$_2$SO$_4$ to pH <2	P or G	14 days.
Nitrite	Cool, 4°C	P or G	48 hours.
Selenium	Conc HNO$_3$ to pH <2	P or G	6 months.
Thallium	Conc HNO$_3$ to pH <2	P or G	6 months.

[1] If HNO$_3$ cannot be used because of shipping restrictions, sample may be initially preserved by icing and immediately shipping it to the laboratory. Upon receipt in the laboratory, the sample must be acidified with conc HNO$_3$ to pH <2 and held for 16 hours before analysis.

[2] P=plastic, hard or soft; G=glass, hard or soft.

[3] In all cases, samples should be analyzed as soon after collection as possible.

[4] See method(s) for the information for preservation.

(6) Analysis under this section shall only be conducted by laboratories that have been certified by EPA or the State. Laboratories may conduct sample analysis under provisional certification until January 1, 1996. To receive certification to conduct analyses for antimony, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite and selenium and thallium, the laboratory must:

(i) Analyze Performance Evaluation samples which include those substances provided by EPA Environmental Monitoring Systems Laboratory or equivalent samples provided by the State.

(ii) Achieve quantitative results on the analyses that are within the following acceptance limits:

Contaminant	Acceptance limit
Antimony	6#30 at >0.006 mg/l
Asbestos	2 standard deviations based on study statistics.
Barium	±15% at >0.15 mg/l
Beryllium	±15% at >0.001 mg/l
Cadmium	±20% at >0.002 mg/l
Chromium	±15% at >0.01 mg/l
Cyanide	±25% at >0.1 mg/l
Fluoride	±10% at >1 to 10 mg/l
Mercury	±30% at >0.0005 mg/l
Nickel	±15% at >0.01 mg/l
Nitrate	±10% at >0.4 mg/l
Nitrite	±15% at >0.4 mg/l

Contaminant	Acceptance limit
Selenium	±20% at ≥ 0.01 mg/1
Thallium	±30% at ≥ 0.002 mg/1

* * * * *

6. Section 141.24 is amended by revising paragraph (f) introductory text, paragraphs (f) introductory text, paragraphs (f)(4), (f)(5), (f)(7), and (f)(10), (f)(11), introductory text, (f)(12), the introductory texts of (f)(14), (f)(15) and (f)(16) revising (f) (17) and (18), (h)(10), (h)(12)(ii)–(iv), (h)(12)(vi)–(viii), (h)(18), (h)(19)(i)(B), and adding paragraphs (h)(12)(ix)–(xiv) to read as follows:

§ 141.24 Organic chemicals other than total trialomethanes, sampling and analytical requirements.

* * * * *

(f) Beginning with the initial compliance period, analysis of the contaminants listed in § 141.61(a) (1) through (21) for the purpose of determining compliance with the maximum contaminant level shall be conducted as follows:

* * * * *

(4) Each community and non-transient non-community water system shall take four consecutive quarterly samples for each contaminant listed in § 141.61(a) (2) through 21 during each compliance period, beginning in the initial compliance period.

(5) If the initial monitoring for contaminants listed in § 141.61(a) (1) through (8) and the monitoring for the contaminants listed in § 141.61(a) (9) through (21) as allowed in paragraph (f)(18) has been completed by December 31, 1992, and the system did not detect any contaminant listed in § 141.61(a) (1) through (21), then each ground and surface water system shall take one sample annually beginning with the initial compliance period.

* * * * *

(7) Each community and non-transient ground water system which does not detect a contaminant listed in § 141.61(a) (1) through (21) may apply to the State for a waiver from the requirements of paragraphs (f)(5) and (f)(6) of this section after completing the initial monitoring. (For purposes of this section, detection is defined as >0.0005 mg/l.) A waiver shall be effective for no more than six years (two compliance periods). States may also issue waivers to small systems for the initial round of monitoring for 1,2,4-trichlorobenzene.

* * * * *

(10) Each community and non-transient surface water system which does not detect a contaminant listed in § 141.61(a) (1) through (21) may apply to the State for a waiver from the requirements of (f)(5) of this section after completing the initial monitoring. Composite samples from a maximum of five sampling points are allowed, provided that the detection limit of the method used for analysis is less than one-fifth of the MCL. Systems meeting this criterion must be determined by the State to be non-vulnerable based on a vulnerability assessment during each compliance period. Each system receiving a waiver shall sample at the frequency specified by the State (if any).

(11) If a contaminant listed in § 141.61(a) (2) through (21) is detected at a level exceeding 0.0005 mg/l in any sample, then:

* * * * *

(12) Systems which violate the requirements of § 141.61(a) (1) through (21), as determined by paragraph (f)(15) of this section, must monitor quarterly. After a minimum of four consecutive quarterly samples which show the system is in compliance as specified in paragraph (f)(15) of this section the system and the State determines that the system is reliably and consistently below the maximum contaminant level, the system may monitor at the frequency and times specified in paragraph (f)(11)(iii) of this section.

* * * * *

(14) The State may reduce the total number of samples a system must analyze by allowing the use of compositing. Composite samples from a maximum of five sampling points are allowed, provided that the detection limit of the method used for analysis is less than one-fifth of the MCL. Compositing of samples must be done in the laboratory and analyzed within 14 days of sample collection.

* * * * *

(15) Compliance with § 141.61(a) (1) through (21) shall be determined based on the analytical results obtained at each sampling point.

* * * * *

(16) Analysis for the contaminants listed in § 141.61(a) (1) through (21) shall be conducted using the following EPA methods or their equivalent as approved by EPA. These methods are contained in Methods for the Determination of Organic Compounds in Drinking Water, EPA/600/4–88/039, and are available from the National Technical Information Service (NTIS) NTIS PB91–231480 and PB91–146027, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800–336–4700.

* * * * *

(17) Analysis under this section shall only be conducted by laboratories that are certified by EPA or the State according to the following conditions (laboratories may conduct sample analysis under provisional certification until January 1, 1996):

(i) To receive certification to conduct analyses for the contaminants in § 141.61(a) (2) through (21) the laboratory must:

(A) Analyze Performance Evaluation samples which include these substances provided by EPA Environmental Monitoring Systems Laboratory or equivalent samples provided by the State.

(B) Achieve the quantitative acceptance limits under paragraphs (f)(17)(i) (C) and (D) of this section for at least 80 percent of the regulated organic chemicals listed in § 141.61(a) (2) through (21).

(C) Achieve quantitative results on the analyses performed under paragraph (f)(17)(i)(A) of this section that are within ±20% of the actual amount of the substances in the Performance Evaluation sample when the actual amount is greater than or equal to 0.010 mg/l.

(D) Achieve quantitative results on the analyses performed under paragraph (f)(17)(i)(A) of this section that are within ±40 percent of the actual amount of the substances in the Performance Evaluation sample when the actual amount is less than 0.010 mg/l.

(E) Achieve a method detection limit of 0.0005 mg/l, according to the procedures in Appendix B of Part 136.

(ii) To receive certification for vinyl chloride, the laboratory must:

(A) Analyze Performance Evaluation samples provided by EPA Environmental Monitoring Systems Laboratory or equivalent samples provided by the State.

(B) Achieve quantitative results on the analyses performed under paragraph (f)(17)(ii)(A) of this section that are within ±40 percent of the actual amount of vinyl chloride in the Performance Evaluation sample.

(C) Achieve a method detection limit of 0.0005 mg/l, according to the procedures in appendix B of part 136.

(D) Obtain certification for the contaminants listed in § 141.61(a)(2) through (21).

(18) States may allow the use of monitoring data collected after January 1, 1988, required under section 1445 of the Act for purposes of initial monitoring compliance. If the data are generally consistent with the other requirements of this section, the State may use these data (i.e., a single sample rather than four quarterly samples) to satisfy the initial monitoring requirement of

paragraph (f)(4) of this section. Systems which use grandfathered samples and did not detect any contaminant listed § 141.61(a)(2) through (21) shall begin monitoring annually in accordance with paragraph (f)(5) of this section beginning with the initial compliance period.

* * * * *

(h) * * *

(10) The State may reduce the total number of samples a system must analyze by allowing the use of compositing. Composite samples from a maximum of five sampling points are allowed, provided that the detection limit of the method used for analysis is less than one-fifth of the MCL. Compositing of samples must be done in the laboratory and analyzed within 14 days of sample collection.

* * * * *

(12) * * *

(ii) Method 505, "Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl Products (Aroclors) in Water by Microextraction and Gas Chromatography." Method 505 can be used to measure alachlor, atrazine, chlordane, endrin, heptachlor, heptachlor epoxide, hexachlorobenzene, hexachlorocyclopentadiene, lindane, methoxychlor, toxaphene and simazine. Method 505 can be used as a screen for PCBs.

(iii) Method 507, "Determination of Nitrogen- and Phosphorus-Containing Pesticides in Ground Water by Gas Chromatography with a Nitrogen-Phosphorus Detector." Method 507 can be used to measure alachlor, atrazine and simazine.

(iv) Method 508, "Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector." Method 508 can be used to measure chlordane, endrin, heptachlor, heptachlor epoxide, hexachlorobenzene, lindane, methoxychlor and toxaphene. Method 508 can be used as a screen for PCBs.

* * * * *

(vi) Method 515.1, "Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector." Method 515.1 can be used to measure 2,4-D, dalapon, dinoseb, pentachlorophenol, picloram and 2,4,5-TP (Silvex).

(vii) Method 525.1, "Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry." Method 525.1 can be used to measure alachlor, atrazine, chlordane, di(2-ethylhexyl)adipate, di(2-ethylhexyl)phthalate, endrin, heptachlor, heptachlor epoxide, hexachlorobenzene,

hexachlorocyclopentadiene, lindane, methoxychlor, pentachlorphenol, polynuclear aromatic hydrocarbons, simazine, and toxaphene.

(viii) Method 531.1, "Measurement of N-Methyl Carbamoyloximes and N-Methyl Carbamates in Water by Direct Aqueous Injection HPLC with Post-Column Derivatization." Method 531.1 can be used to measure aldicarb, aldicarb sulfoxide, aldicarb sulfone, carbofuran and oxamyl.

(ix) Method 1613, "Tetra- through Octa- Chlorinated Dioxins and Furans by Isotope Dilution." Method 1613 can be used to measure 2,3,7,8-TCDD (dioxin). This method is available from USEPA-OST, Sample Control Center, P.O. Box 1407, Alexandria, VA 22313.

(x) Method 547, "Analysis of Glyphosate in Drinking Water by Direct Aqueous Injection HPLC with Post-Column Derivatization" Method 547 can be used to measure glyphosate.

(xi) Method 548, "Determination of Endothall in Aqueous Samples." Method 548 can be used to measure endothall.

(xii) Method 549, "Determination of Diquat and Paraquat in Drinking Water by High Performance Liquid Chromatography with Ultraviolet Detection." Method 549 can be used to measure diquat.

(xiii) Method 550, "Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Liquid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection". Method 550 can be used to measure benzo(a)pyrene and other polynuclear aromatic hydrocarbons.

(xiv) Method 550.1, "Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Solid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection". Method 550.1 can be used to measure benzo(a)pyrene and other polynuclear aromatic hydrocarbons.

* * * * *

(18) Detection as used in this paragraph shall be defined as greater than or equal to the following concentrations for each contaminant.

Contaminant	Detection limit (mg/l)
Alachlor	.0002
Aldicarb	.0005
Aldicarb sulfoxide	.0005
Aldicarb sulfone	.0008
Atrazine	.0001
Benzo[a]pyrene	.00002
Carbofuran	.0009
Chlordane	.0002
Dalapon	.001
Dibromochloropropane (DBCP)	.00002
Di (2-ethylhexyl) adipate	.0006
Di (2-ethylhexyl) phthalate	.0006

Contaminant	Detection limit (mg/l)
Dinoseb	.0002
Diquat	.0004
2,4-D	.0001
Endothall	.009
Endrin	.00001
Ethylene dibromide (EDB)	.00001
Glyphosate	.006
Heptachlor	.00004
Heptachlor epoxide	.00002
Hexachlorobenzene	.0001
Hexachlorocyclopentadiene	.0001
Lindane	.00002
Methoxychlor	.0001
Oxamyl	.002
Picloram	.0001
Polychlorinated biphenyls (PCBs) (as decachlorobiphenyl)	.0001
Pentachlorophenol	.00004
Simazine	.00007
Toxaphene	.001
2,3,7,8-TCDD (Dioxin)	.000000005
2,4,5-TP (Silvex)	.0002

* * * * *

(19) * * *

(i) * * *

(B) Achieve quantitative results on the analyses that are within the following acceptance limits:

Contaminant	Acceptance limits (percent)
DBCP	±40
EDB	±40
Alachlor	±45
Atrazine	±45
Benzo[a]pyrene	2 standard deviations
Carbofuran	±45
Chlordane	±45
Dalapon	2 standard deviations
Di(2-ethylhexyl)adipate	2 standard deviations
Di(2-ethylhexyl)phthalate	2 standard deviations
Dinoseb	2 standard deviations
Diquat	2 standard deviations
Endothall	2 standard deviations
Endrin	±30
Glyphosate	2 standard deviations
Heptachlor	±45
Heptachlor epoxide	±45
Hexachlorobenzene	2 standard deviations
Hexachloro-cyclopentadiene	2 standard deviations
Lindane	±45
Methoxychlor	±45
Oxamyl	2 standard deviations
PCBs (as Decachlorobiphenyl)	0–200
Picloram	2 standard deviations
Simazine	2 standard deviations
Toxaphene	±45
Aldicarb	2 standard deviations
Aldicarb sulfoxide	2 standard deviations
Aldicarb sulfone	2 standard deviations
Pentachlorophenol	±50
2,3,7,8-TCDD (Dioxin)	2 standard deviations
2,4-D	±50
2,4,5-TP (Silvex)	±50

* * * * *

7. Section 141.32 is amended by adding paragraphs (e)(53) through (75) to read as follows:

§ 141.32 Public notification.

*   *   *   *   *

(e)* * *

(53) *Antimony*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that antimony is a health concern at certain levels of exposure. This inorganic chemical occurs naturally in soils, ground water and surface waters and is often used in the flame retardant industry. It is also used in ceramics, glass, batteries, fireworks and explosives. It may get into drinking water through natural weathering of rock, industrial production, municipal waste disposal or manufacturing processes. This chemical has been shown to decrease longevity, and altered blood levels of cholesterol and glucose in laboratory animals such as rats exposed to high levels during their lifetimes. EPA has set the drinking water standard for antimony at 0.006 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to antimony.

(54) *Beryllium*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that beryllium is a health concern at certain levels of exposure. This inorganic metal occurs naturally in soils, ground water and surface waters and is often used in electrical equipment and electrical components. It generally gets into water from runoff from mining operations, discharge from processing plants and improper waste disposal. Beryllium compounds have been associated with damage to the bones and lungs and induction of cancer in laboratory animals such as rats and mice when the animals are exposed at high levels over their lifetimes. There is limited evidence to suggest that beryllium may pose a cancer risk via drinking water exposure. Therefore, EPA based the health assessment on noncancer effects with an extra uncertainty factor to account for possible carcinogenicity. Chemicals that cause cancer in laboratory animals also may increase the risk of cancer in humans who are exposed over long periods of time. EPA has set the drinking water standard for beryllium at 0.004 part per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to beryllium.

(55) *Cyanide*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that cyanide is a health concern at certain levels of exposure. This inorganic chemical is used in electroplating, steel processing, plastics, synthetic fabrics and fertilizer products. It usually gets into water as a result of improper waste disposal. This chemical has been shown to damage the spleen, brain and liver of humans fatally poisoned with cyanide. EPA has set the drinking water standard for cyanide at 0.2 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to cyanide.

(56) *Nickel*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that nickel poses a health concern at certain levels of exposure. This inorganic metal occurs naturally in soils, ground water and surface waters and is often used in electroplating, stainless steel and alloy products. It generally gets into water from mining and refining operations. This chemical has been shown to damage the heart and liver in laboratory animals when the animals are exposed to high levels over their lifetimes. EPA has set the drinking water standard at 0.1 parts per million (ppm) for nickel to protect against the risk of these adverse effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to nickel.

(57) *Thallium*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that thallium is a health concern at certain high levels of exposure. This inorganic metal is found naturally in soils and is used in electronics, pharmaceuticals, and the manufacture of glass and alloys. This chemical has been shown to damage the kidney, liver, brain and intestines of laboratory animals when the animals are exposed at high levels over their lifetimes. EPA has set the drinking water standard for thallium at 0.002 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to thallium.

(58) *Benzo[a]pyrene*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that benzo[a]pyrene is a health concern at certain levels of exposure. Cigarette smoke and charbroiled meats are common source of general exposure. The major source of benzo[a]pyrene in drinking water is the leaching from coal tar lining and sealants in water storage tanks. This chemical has been shown to cause cancer in animals such as rats and mice when the animals are exposed at high levels. EPA has set the drinking water standard for benzo[a]pyrene at 0.0002 parts per million (ppm) to protect against the risk of cancer. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to benzo[a]pyrene.

(59) *Dalapon*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that dalapon is a health concern at certain levels of exposure. This organic chemical is a widely used herbicide. It may get into drinking water after application to control grasses in crops, drainage ditches and along railroads. This chemical has been shown to cause damage to the kidney and liver in laboratory animals when the animals are exposed to high levels over their lifetimes. EPA has set the drinking water standard for dalapon at 0.2 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to dalapon.

(60) *Dichloromethane*. The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that dichloromethane (methylene chloride) is a health concern at certain levels of exposure. This organic chemical is a widely used solvent. It is used in the manufacture of paint remover, as a metal degreaser and as an aerosol propellant. It generally gets into drinking water after improper discharge of waste disposal. This chemical has been shown to cause cancer in laboratory animals such as rats and mice when the animals are exposed at high levels over their lifetimes. Chemicals that cause cancer in laboratory animals also may increase the risk of cancer in humans who are exposed over long periods of time. EPA has set the drinking water standard for dichloromethane at 0.005 parts per million (ppm) to reduce the risk of cancer or other adverse health effects which have been observed in laboratory animals. Drinking water which meets this standard is associated with little to none of this risk and should be considered safe with respect to dichloromethane.

(61) *Di (2-ethylhexyl)adipate*. The United States Environmental Protection Agency (EPA) sets drinking water

standards and has determined that di(2-ethylhexyl)adipate is a health concern at certain levels of exposure. Di(2-ethylhexyl)adipate is a widely used plasticizer in a variety of products, including synthetic rubber, food packaging materials and cosmetics. It may get into drinking water after improper waste disposal. This chemical has been shown to damage liver and testes in laboratory animals such as rats and mice exposed to high levels. EPA has set the drinking water standard for di(2-ethylhexyl)adipate at 0.4 parts per million (ppm) to protect against the risk of adverse health effects. Drinking water which meets the EPA standards is associated with little to none of this risk and should be considered safe with respect to di(2-ethylhexyl)adipate.

(62) *Di(2-ethylhexyl)phthalate.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that di(2-ethylhexyl)phthalate is a health concern at certain levels of exposure. Di(2-ethylhexyl)phthalate is a widely used plasticizer, which is primarily used in the production of polyvinyl chloride (PVC) resins. It may get into drinking water after improper waste disposal. This chemical has been shown to cause cancer in laboratory animals such as rats and mice exposed to high levels over their lifetimes. EPA has set the drinking water standard for di(2-ethylhexyl)phthalate at 0.004 parts per million (ppm) to reduce the risk of cancer or other adverse health effects which have been observed in laboratory animals. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to di(2-ethylhexyl)phthalate.

(63) *Dinoseb.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that dinoseb is a health concern at certain levels of exposure. Dinoseb is a widely used pesticide and generally gets into drinking water after application on orchards, vineyards and other crops. This chemical has been shown to damage the thyroid and reproductive organs in laboratory animals such as rats exposed to high levels. EPA has set the drinking water standard for dinoseb at 0.007 parts per million (ppm) to protect against the risk of adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to dinoseb.

(64) *Diquat.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has

determined that diquat is a health concern at certain levels of exposure. This organic chemical is a herbicide used to control terrestrial and aquatic weeds. It may get into drinking water by runoff into surface water. This chemical has been shown to damage the liver, kidney and gastrointestinal tract and causes cataract formation in laboratory animals such as dogs and rats exposed at high levels over their lifetimes. EPA has set the drinking water standard for diquat at 0.02 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to diquat.

(65) *Endothall.* The United States Environmental Protection Agency (EPA) has determined that endothall is a health concern at certain levels of exposure. This organic chemical is a herbicide used to control terrestrial and aquatic weeds. It may get into water by runoff into surface water. This chemical has been shown to damage the liver, kidney, gastrointestinal tract and reproductive system of laboratory animals such as rats and mice exposed at high levels over their lifetimes. EPA has set the drinking water standard for endothall at 0.1 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to endothall.

(66) *Endrin.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that endrin is a health concern at certain levels of exposure. This organic chemical is a pesticide no longer registered for use in the United States. However, this chemical is persistent in treated soils and accumulates in sediments and aquatic and terrestrial biota. This chemical has been shown to cause damage to the liver, kidney and heart in laboratory animals such as rats and mice when the animals are exposed at high levels over their lifetimes. EPA has set the drinking water standard for endrin at 0.002 parts per million (ppm) to protect against the risk of these adverse health effects which have been observed in laboratory animals. Drinking water that meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to endrin.

(67) *Glyphosate.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that glyphosate is a health

concern at certain levels of exposure. This organic chemical is a herbicide used to control grasses and weeds. It may get into drinking water by runoff into surface water. This chemical has been shown to cause damage to the liver and kidneys in laboratory animals such as rats and mice when the animals are exposed at high levels over their lifetimes. EPA has set the drinking water standard for glyphosate at 0.7 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to glyphosate.

(68) *Hexachlorobenzene.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that hexachlorobenzene is a health concern at certain levels of exposure. This organic chemical is produced as an impurity in the manufacture of certain solvents and pesticides. This chemical has been shown to cause cancer in laboratory animals such as rats and mice when the animals are exposed to high levels during their lifetimes. Chemicals that cause cancer in laboratory animals also may increase the risk of cancer in humans who are exposed over long periods of time. EPA has set the drinking water standard for hexachlorobenzene at 0.001 parts per million (ppm) to protect against the risk of cancer and other adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to hexachlorobenzene.

(69) *Hexachlorocyclopentadiene.* The United States Environmental Protection Agency (EPA) establishes drinking water standards and has determined that hexachlorocyclopentadiene is a health concern at certain levels of exposure. This organic chemical is used as an intermediate in the manufacture of pesticides and flame retardants. It may get into water by discharge from production facilities. This chemical has been shown to damage the kidney and the stomach of laboratory animals when exposed at high levels over their lifetimes. EPA has set the drinking water standard for hexachlorocyclopentadiene at 0.05 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to hexachlorocyclopentadiene.

(70) *Oxamyl.* The United States Environmental Protection Agency (EPA) establishes drinking water standards

and has determined that oxamyl is a health concern at certain levels of exposure. This organic chemical is used as a pesticide for the control of insects and other pests. It may get into drinking water by runoff into surface water or leaching into ground water. This chemical has been shown to damage the kidneys of laboratory animals such as rats when exposed at high levels over their lifetimes. EPA has set the drinking water standard for oxamyl at 0.2 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to oxamyl.

(71) *Picloram.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that picloram is a health concern at certain levels of exposure. This organic chemical is used as a pesticide for broadleaf weed control. It may get into drinking water by runoff into surface water or leaching into ground water as a result of pesticide application and improper waste disposal. This chemical has been shown to cause damage to the kidneys and liver in laboratory animals such as rats when the animals are exposed at high levels over their lifetimes. EPA has set the drinking water standard for picloram at 0.5 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to picloram.

(72) *Simazine.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that simazine is a health concern at certain levels of exposure. This organic chemical is a herbicide used to control annual grasses and broadleaf weeds. It may leach into ground water or runs off into surface water after application. This chemical may cause cancer in laboratory animals such as rats and mice exposed at high levels during their lifetimes. Chemicals that cause cancer in laboratory animals also may increase the risk of cancer in humans who are exposed over long periods of time. EPA has set the drinking water standard for simazine at 0.004 parts per million (ppm) to reduce the risk of cancer or other adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to simazine.

(73) *1,2,4-Trichlorobenzene.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that 1,2,4-trichlorobenzene is a health concern at certain levels of exposure. This organic chemical is used as a dye carrier and as a precursor in herbicide manufacture. It generally gets into drinking water by discharges from industrial activities. This chemical has been shown to cause damage to several organs, including the adrenal glands. EPA has set the drinking water standard for 1,2,4-trichlorobenzene at 0.07 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to 1,2,4-trichlorobenzene.

(74) *1,1,2-Trichloroethane.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined 1,1,2-trichloroethane is a health concern at certain levels of exposure. This organic chemical is an intermediate in the production of 1,1-dichloroethylene. It generally gets into water by industrial discharge of wastes. This chemical has been shown to damage the kidney and liver of laboratory animals such as rats exposed to high levels during their lifetimes. EPA has set the drinking water standard for 1,1,2-trichloroethane at 0.005 parts per million (ppm) to protect against the risk of these adverse health effects. Drinking water which meets the EPA standard is associated with little to none of this risk and should be considered safe with respect to 1,1,2-trichloroethane.

(75) *2,3,7,8-TCDD (Dioxin).* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that dioxin is a health concern at certain levels of exposure. This organic chemical is an impurity in the production of some pesticides. It may get into drinking water by industrial discharge of wastes. This chemical has been shown to cause cancer in laboratory animals such as rats and mice when the animals are exposed at high levels over their lifetimes. Chemicals that cause cancer in laboratory animals also may increase the risk of cancer in humans who are exposed over long periods of time. EPA has set the drinking water standard for dioxin at 0.00000003 parts per million (ppm) to reduce the risk of cancer or other adverse health effects which have been observed in laboratory animals. Drinking water which meets this standard is associated with little to none of this risk and should be considered safe with respect to dioxin.

8. Section 141.40 is amended by revising paragraph (e), revising paragraph (f), revising paragraphs (g) and (h), and revising paragraphs (n) (11) and (12) including the tables to read as follows:

§ 141.40 Special monitoring for organic chemicals.

* * * * *

(e) Community water systems and non-transient, non-community water systems shall monitor for the following contaminants except as provided in paragraph (f) of this section:

(1) Chloroform
(2) Bromodichloromethane
(3) Chlorodibromomethane
(4) Bromoform
(5) Chlorobenzene
(6) m-Dichlorobenzene
(8) 1,1-Dichloropropene
(9) 1,1-Dichloroethane
(10) 1,1,2,2-Tetrachloroethane
(11) 1,3-Dichloropropane
(12) Chloromethane
(13) Bromomethane
(14) 1,2,3-Trichloropropane
(15) 1,1,1,2-Tetrachloroethane
(16) Chloroethane
(17) 2,2-Dichloropropane
(18) o-Chlorotoluene
(19) p-Chlorotoluene
(20) Bromobenzene
(21) 1,3-Dichloropropene

(f) [Reserved]

(g) Analysis under this section shall be conducted using the recommended EPA methods as follows, or their equivalent as determined by EPA: 502.1, "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography," 503.1, "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography," 524.1, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry," 524.2, "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry, or 502.2, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series." These methods are contained in "Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water," September 1986, available from the Drinking Water Public Docket or the National Technical Information Service (NTIS), NTIS PB91–231480 and PB91–146027, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800–336–4700.

(h) Analysis under this section shall only be conducted by laboratories approved under § 141.24(g)(11).

*   *   *   *   *

(n) * * *

(11) List of Unregulated Organic Contaminants:

Organic contaminants	EPA analytical method
Aldrin	505, 508, and 525.
Butachlor	507, 525.
Carbaryl	581.1.
Dicamba	515.1.
Dieldrin	505, 508, and 525.
3-Hydroxycarbofuran	581.1.
Methomyl	531.1.
Metolachlor	507, 525.
Metribuzin	507, 508, and 525.
Propachlor	507, 525.

(12) List of Unregulated Inorganic Contaminants:

Inorganic contaminants	EPA analytical method
Sulfate	Colorimetric.

9. Section 141.50 is amended by adding paragraphs (a)(19) through (a)(23) and paragraphs (b)(21) through (b)(33) in the table in paragraphs (b) as follows:

§ 141.50   Maximum contaminant level goals for organic chemicals.

(a) * * *

(19) Benzo[a]pyrene

(20) Dichloromethane (methylene chloride)

(21) Di(2-ethylhexyl)phthalate

(22) Hexachlorobenzene

(23) 2,3,7,8-TCDD (Dioxin)

(b) * * *

Contaminant	MCLG (mg/1)
* * * * *	
(21) Dalapon	0.2
(22) Di(2-ethylhexyl)adipate	.4
(23) Dinoseb	.007
(24) Diquat	.02
(25) Endothall	.1
(26) Endrin	.002
(27) Glyphosate	.7
(28) Hexachlorocyclopentadiene	.05
(29) Oxamyl (Vydate)	.2
(30) Picloram	.5
(31) Simazine	.004
(32) 1,2,4-Trichlorobenzene	.07
(33) 1,1,2-Trichloroethane	.003

10. Section 141.51 is amended by adding entries (b)(11) through (b)(15) as follows:

§ 141.51   Maximum contaminant level goals for inorganic contaminants.

(b) * * *

Contaminant	MCLG (mg/1)
* * * * *	
(11) Antimony	0.006
(12) Beryllium	.004
(13) Cyanide (as free Cyanide)	.2
(14) Nickel	.1
(15) Thallium	.0005

11. Section 141.60 is amended by adding paragraphs (a)(3) and (b)(3) to read as follows:

§ 141.60   Effective dates.

(a) * * *

(3) The effective date for paragraphs (a)(19) through (a)(21) and (c)(19) through (c)(33) of § 141.61 is January 17, 1994.

(b) * * *

(3) The effective date for paragraphs (b)(11) through (b)(15) of § 141.62 is January 17, 1994.

12. Section 141.61 is amended by adding paragraphs (a)(19)–(21); by revising paragraph (b) including the table; by revising the introductory text to paragraph (c); and by adding paragraphs (c)(19)–(33).

§ 141.61   Maximum contaminant levels for organic contaminants.

*   *   *   *   *

CAS No.	Contaminant	MCL (mg/l)
* * * * *		
(19) 75-09-2	Dichloromethane	0.005
(20) 120-82-1	1,2,4-Trichloro-benzene	.07
(21) 79-00-5	1,1,2-Trichloro-ethane	.005

(b) The Administrator, pursuant to section 1412 of the Act, hereby identifies as indicated in the Table below granular activated carbon (GAC), packed tower aeration (PTA), or oxidation (OX) as the best technology treatment technique, or other means available for achieving compliance with the maximum contaminant level for synthetic organic contaminants identified in paragraphs (a) and (c) of this section:

BAT FOR ORGANIC CONTAMINANTS LISTED IN SECTION 141.61(A) AND (C)

CAS No.	Contaminant	GAC	PTA	OX
50-32-8	Benzo[a]pyrene	X		
75-99-0	Dalapon	X		
75-09-2	Dichloromethane		X	
103-23-1	Di (2-ethylhexyl) adipate	X	X	
117-81-7	Di (2-ethylhexyl) phthalate	X		
88-85-7	Dinoseb	X		
85-00-7	Diquat	X		
145-73-3	Endothall	X		
72-20-8	Endrin	X		
1071-53-6	Glyphosate			X
118-74-1	Hexachlorobenzene	X		
77-47-3	Hexachlorocyclopentadiene	X	X	
23135-22-0	Oxamyl (Vydate)	X		
1918-02-1	Picloram	X		
122-34-9	Simazine	X		
120-82-1	1,2,4-Trichlorobenzene	X	X	
79-00-5	1,1,2-Trichloroethane	X	X	
1746-01-6	2,3,7,8-TCDD (Dioxin)	X		

(c) The following maximum contaminant levels for synthetic organic contaminants apply to community water systems and non-transient, non-community water systems:

*   *   *   *   *

	CAS No.	Contaminant	MCL (mg/1)
(19)...	*	*	*
(20)...	50–32–8	Benzo[a]pyrene.........................	0.0002
(21)...	75–99–0	Dalapon....................................	0.2
(22)...	103–23–1	Di(2-ethylhexyl) adipate...........	0.4
(23)...	117–81–7	Di(2-ethylhexyl) phthalate.........	0.006
(24)...	88–85–7	Dinoseb....................................	0.007
(25)...	85–00–7	Diquat.......................................	0.02
(26)...	145–73–3	Endothall..................................	0.1
(27)...	72–20–8	Endrin......................................	0.002
(28)...	1071–53–6	Glyphosate..............................	0.7
(29)...	118–74–1	Hexacholorbenzene.................	0.001
(30)...	77–47–4	Hexachlorocyclopentadiene......	0.05
(31)...	23135–22–0	Oxamyl (Vydate).....................	0.2
(32)...	1918–02–1	Picloram..................................	0.5
(33)...	122–34–9	Simazine..................................	0.004
	1746–01–6	2,3,7,8-TCDD (Dioxin).............	3 × 10⁻⁸

3. Section 141.62 is amended by revising the introductory text to paragraph (b); by adding paragraphs (b)(11) through (b)(15); and by revising paragraph (c), including the table, to read as follows:

§ 141.62 Maximum contaminant levels for inorganic contaminants.

* * * * *

(b) The maximum contaminant levels for inorganic contaminants specified in paragraphs (b)(2)—(6), (b)(10), and (b)(11)—(15) of this section apply to community water systems and non-transient, non-community water systems. The maximum contaminant level specified in paragraph (b)(1) of this section only applies to community water systems. The maximum contaminant levels specified in (b)(7), (b)(8), and (b)(9) of this section apply to community water systems; non-transient, non-community water systems; and transient non-community water systems.

Contaminant	MCL (mg/l)
(11) Antimony	0.006
(12) Beryllium..	0.004
(13) Cyanide (as free Cyanide)...	0.2
(14) Nickel...	0.1
(15) Thallium...	0.002

(c) The Administrator, pursuant to Section 1412 of the Act, hereby identifies the following as the best technology, treatment technique, or other means available for achieving compliance with the maximum contaminant levels for inorganic contaminants identified in paragraph (b) of this section, except fluoride:

BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(B)

Chemical Name	BAT(s)
Antimony	2,7
Asbestos.............................	2,3,8
Barium................................	5,6,7,9
Beryllium.............................	1,2,5,6,7
Cadmium.............................	2,5,6,7
Chromium............................	2,5,6 ²,7
Cyanide...............................	5,7,10
Mercury...............................	2 ¹,4,6 ¹,7 ¹
Nickel..................................	5,6,7
Nitrate.................................	5,7,9
Nitrite..................................	5,7
Selenium.............................	1,2 ³,6,7,9
Thallium...............................	1,5

¹ BAT only if influent Hg concentrations ≤ 10µg/1.
² BAT for Chromium III only.
³ BAT for Selenium IV only.

Key to BATS in Table

1 = Activated Alumina
2 = Coagulation/Filtration
3 = Direct and Diatomite Filtration
4 = Granular Activated Carbon
5 = Ion Exchange
6 = Lime Softening
7 = Reverse Osmosis
8 = Corrosion Control
9 = Electrodialysis
10 = Chlorine
11 = Ultraviolent

14. Section 141.89(a) table is amended by revising footnote 9 to read as follows:

§ 141.89 Analytical methods.

* * * * *

[9] For analyzing lead and copper, the technique applicable to total metals must be used and samples cannot be filtered. Samples that contain less than 1 NTU (nephelometric turbidity unit) and are properly preserved (conc HNO₃ to pH < 2) may be analyzed directly (without digestion) for total metals; otherwise, digestion is required. Turbidity must be measured on the preserved samples just prior to when metal analysis is initiated. When digestion is required, the 'total recoverable' technique as defined in the method must be used.

* * * * *

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300g. 300g–1. 300g–2. 300g–3. 300g–4. 300g–5. 300g–6. 300j–4 and 300j–9.

2. Section 142.16 is amended by revising the introductory text to paragraph (e), and revising paragraph (e)(2) to read as follows:

§ 142.16 Special Primary Requirements.

* * * * *

(e) An application for approval of a State program revision which adopts the requirements specified in §§ 141.11. 141.23, 141.24, 141.32, 141.40, 141.61 and 141.62 must contain the following (in addition to the general primacy requirements enumerated elsewhere in this Part, including the requirement that State regulations be at least as stringent as the federal requirements):

(2) A monitoring plan for the initial monitoring period by which the State will assure all systems complete the required initial monitoring within the regulatory deadlines.

Note: States may update their monitoring plan submitted under the Phase II Rule or simply note in their application that they will use the same monitoring plan for the Phase V Rule.

(i) The initial monitoring plan must describe how systems will be scheduled during the initial monitoring period and demonstrate that the analytical workload on certified laboratories for each of the three years has been taken into account, to assure that the State's plan will result in a high degree of monitoring compliance and that as a result there is a high probability of compliance and will be updated as necessary.

(ii) The State must demonstrate that the initial monitoring plan is enforceable under State law.

3. Section 142.62 is amended by revising paragraphs (a) and (b) to read as follows:

§ 142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

(a) The Administrator, pursuant to section 1415(a)(1)(A) of the Act hereby identifies the technologies listed in paragraphs (a)(1) through (a)(54) of this section as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for organic chemicals listed in §§ 141.61 (a) and (c):

Contaminant	Best available technologies		
	PAT [1]	GAO [2]	OX [3]
(1) Benzene	X	X	
(2) Carbon tetrachloride	X	X	
(3) 1,2-Dichloroethane	X	X	
(4) Trichloroethylene	X	X	
(5) para-Dichlorobenzene	X	X	
(6) 1,1-Dichloroethylene	X	X	
(7) 1,1,1-Trichloroethane	X	X	
(8) Vinyl chloride	X		
(9) cis-1,2-Dichloroethylene	X		
(10) 1,2-Dichloropropane	X	X	
(11) Ethylbenzene	X	X	
(12) Monochlorobenzene	X	X	
(13) o-Dichlorobenzene	X	X	
(14) Styrene	X	X	
(15) Tetrachloroethylene	X	X	
(16) Toluene	X	X	
(17) trans-1,2-Dichloroethylene	X	X	
(18) Xylenes (total)	X	X	
(19) Alachlor	X	X	
(20) Aldicarb		X	
(21) Aldicarb sulfoxide		X	
(22) Aldicarb sulfone		X	
(23) Atrazine		X	
(24) Carbofuran		X	
(25) Chlordane		X	
(26) Dibromochloropropane	X	X	
(27) 2,4-D		X	
(28) Ethylene dibromide	X	X	
(29) Heptachlor		X	
(30) Heptachlor epoxide		X	
(31) Lindane		X	
(32) Methoxychlor		X	
(33) PCBs		X	
(34) Pentachlorophenol		X	
(35) Toxaphene		X	
(36) 2,4,5-TP		X	
(37) Benzo[a]pyrene		X	
(38) Dalapone		X	
(39) Dichloromethane	X		
(40) Di(2-ethylhexyl)adipate	X	X	
(41) Di(2-ethylhexyl)phthalate		X	
(42) Dinoseb		X	
(43) Diquat		X	
(44) Endothall		X	
(45) Endrin		X	
(46) Glyphosate			
(47) Hexachlorobenzene			X
(48) Hexachlorocyclopentadiene			X
(49) Oxamyl (Vydate)	X	X	
(50) Picloram		X	
(51) Simazine		X	
(52) 1,2,4-Trichlorobenzene	X	X	
(53) 1,1,2-Trichloroethane	X	X	
(54) 2,3,7,8-TCDD (Dioxin)		X	

[1] Packed Tower Aeration
[2] Granular Activated Carbon
[3] Oxidation (Chlorination or Ozonation)

(b) The Administrator, pursuant to section 1415(a)(1)(A) of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum

contaminant levels for the inorganic chemicals listed in § 141.62:

BAT FOR INORGANIC COMPOUNDS LISTED IN [6] 141.62(B)

Chemical name	BAT(s)
Antimony	2,7
Asbestos	2,3,8
Barium	5,6,7,9
Beryllium	1,2,5,6,7
Cadmium	2,5,6,7
Chromium	2,5,6 [1],7
Cyanide	5,7,10
Mercury	2 [1],4,6 [1],7 [1]
Nickel	5,6,7

BAT FOR INORGANIC COMPOUNDS LISTED IN [6] 141.62(B)—Continued

Chemical name	BAT(s)
Nitrite	5,7,9
Nitrate	5,7
Selenium	1,2 [1],6,7,9
Thallium	1,5

[1] BAT only if influent Hg concentrations < 10μg/1.
[2] BAT for Chromium III only.
[3] BAT for Selenium IV only.

Key to BATS in Table

1 = Activated Alumina

2 = Coagulation/Filtration (not BAT for systems < 500 service connections)
3 = Direct and Diatomite Filtration
4 = Granular Activated Carbon
5 = Ion Exchange
6 = Lime Softening (not BAT for systems < 500 service connections)
7 = Reverse Osmosis
8 = Corrosion Control
9 = Electrodialysis
10 = Chlorine
11 = Ultraviolet

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