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Internal Correspondence
JFW
10-18-83

October 14, 1983

U.S. Environmental Protection Agency (EPA) - National Revised Primary Drinking Water Regulations

REF: (1) JFW correspondence, U.S. Environmental Protection Agency (EPA) - Advance Notice of Proposed Rulemaking on Asbestos in Drinking Water, February 25, 1983

ACTION REQUIRED: Review for information

Background

The Safe Drinking Water Act (SDWA) directs EPA to review the National Interim Primary Drinking Water Regulations and issue National Revised Primary Drinking Water Regulations for contaminants in drinking water. This is the third phase in the evolution of EPA drinking water regulations. During this process (1977, 1980, 1982) the National Academy of Sciences (NAS) was engaged by EPA to assess health effects of various contaminants in drinking water and to propose "recommended maximum contaminant levels (RMCLs)" where "no known or anticipated effects on health of persons" would result. While NAS conducted the toxicological assessments, it declined to develop proposed RMCLs, stating this was a regulatory, rather than a scientific, function. Thus, EPA will use NAS studies and other scientific information to develop and publish RMCLs and "maximum contaminant levels" (MCLs) for substances meriting regulation.

Current Status

On October 5, 1983, EPA published an advance notice of proposed rulemaking (ANPRM) of its intentions to propose National Revised Primary Drinking Water Regulations (enclosed). The questions raised in the ANPRM are:

1. Which contaminants should be regulated?
2. What levels for RMCLs and MCLs would be appropriate?
3. What monitoring and reporting requirements would be appropriate?

In the context of the above issues, the ANPRM requests comments on asbestos in drinking water. The agency's remarks on asbestos are presented on pages 45515 and 45516 of the enclosure. Attention is also directed to page 45517, specifically the section entitled "Corrosion."

AACPP Action Plan

AACPP Strategic Operational Plan SOP-01-03 refers. Staff will meet with Kirkland & Ellis on October 14, 1983 to identify information needs and develop a work plan for preparing industry comments to the ANPRM.

If you have any questions, please do not hesitate to call.

JFW/ajb

Enclosure

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Special Counsel (all states)
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Wednesday
October 5, 1983

Part II

**Environmental
Protection Agency**

National Revised Primary Drinking Water
Regulations; Advance Notice of Proposed
Rulemaking

ENVIRONMENTAL PROTECTION AGENCY

National Revised Primary Drinking Water Regulations

40 CFR Part 141

[WH-FRL 2418-1]

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: EPA is today publishing this advance notice of its intention to propose National Revised Primary Drinking Water Regulations (NPDWR) for organic, inorganic, microbial and radionuclide contaminants in drinking water. The Safe Drinking Water Act (42 USC 300f *et seq.*) (SDWA), following the issuance of National Interim Primary Drinking Water Regulations (i.e., Interim Regulations) directs EPA to issue revised regulations. The foundation of the NPDWR will be a comprehensive reassessment of the Interim Regulations directed toward identifying chemicals in drinking water for which national drinking water regulations would be warranted. Detailed assessments will be made of the experiences since application of the Interim Regulations, occurrence frequency and human exposure potential, human health concerns and basic toxicology, water treatment technologies and costs, analytical chemistry and monitoring methods and implementation options that would optimize public health protection without unnecessary economic burdens on the States and communities.

EPA is issuing this ANPRM as an invitation for the public to comment on all of the technical and regulatory issues that are being examined and requests any information that will assist in the development of the NPDWR.

DATES: Written comments should be submitted by January 3, 1983. A public meeting will be held on December 13, 1983, beginning at 9:00 a.m. in Room 3906, EPA, 401 M St. SW., Washington, D.C. Public technical workshops will be held in the following locations:

Philadelphia, Pennsylvania—September 21-23, 1983

St. Louis, Missouri—October 4-6, 1983

Reno, Nevada—November 1-3, 1983

Orlando, Florida—November 28-30, 1983

ADDRESSES: Send written comments to Comment Clerk, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. A copy of all comments will

be available for review during normal business hours at the EPA, Room 55EB, 401 M Street, SW., Washington, D.C. 20460. It is requested that anyone planning to attend the public meeting (especially those who plan to make statements) register in advance by calling or writing Ms. Arnetta Davis at 202/382-7575, EPA, WH-550, 401 M St., SW., Washington, D.C. 20460. Persons planning to make statements at the meeting are encouraged to submit written copies of their remarks at the time of the meeting.

The public technical workshops will provide a forum for a full discussion of issues and a complete exchange of information and data. Registration for the workshops and additional information can be obtained by contacting AWWA Research Foundation, 6666 West Quincy Ave., Denver, Colorado 80235, which is the grantees conducting the workshops for EPA.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, telephone (202) 382-7575.

SUPPLEMENTARY INFORMATION:

- I. Statutory Requirements
- II. Regulatory Framework
- III. NPDWR: Approaches Under Consideration
- IV. NPDWR: Regulatory Assessments
- V. NPDWR: Specific Considerations
- VI. References
- VII. Request for Comments

I. Statutory Requirements

The Safe Drinking Water Act (42 U.S.C. 300f, *et seq.*) ("SDWA" or "the Act") requires the EPA to publish primary drinking water regulations which:

1. Apply to public water systems,
2. "Specify(s) contaminants which in the judgment of the Administrator, may have any adverse effect on the health of persons" [Section 1401(1), 42 U.S.C. 300g-1], and
3. Specify for each contaminant either (a) maximum contaminant levels (MCLs) or (b) treatment techniques.

A treatment technique requirement would only be set if "it is not economically or technologically feasible" to ascertain the level of a contaminant in drinking water.

In the revised primary drinking water regulations, "recommended maximum contaminant levels" (RMCLs) must also be specified. *RMCLs* are non-enforceable health goals for public water systems. RMCLs are to be set at a level at which, in the Administrator's

judgment, "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". Section 1412(b)(1)(B). Congressional guidance on RMCLs for carcinogens was contained in House Report 93-1185:

... The Administrator must consider the possible impact of synergistic effects, long-term and multi-stage exposures, and the existence of more susceptible groups in the population. Finally, the recommended maximum level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at zero level.

The primary drinking water regulations must also set MCLs. *MCLs are the enforceable standards.* MCLs must be set as close to RMCLs as is feasible. Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)". Section 1412(b)(3).

In addition, the SDWA specifies that primary drinking water regulations contain criteria and procedures to assure a supply of water that complies with the MCLs. Section 1401(1)(D) 42 U.S.C. 300f(1)(D). Section 1445(a) authorizes EPA to require by regulation any public water supplier to keep records, make reports, conduct monitoring and provide such other information as may be required to assist in determining compliance with the SDWA, in evaluating health risks of unregulated contaminants, or in advising the public of such health risks.

The SDWA also requires that the revised primary drinking water regulations be reviewed every three years and amended whenever changes in technology, treatment techniques or other factors permit greater health protection.

The SDWA provides for the issuance of variances to give legal protection to systems that are unable to comply with the regulations, despite the application of treatment technologies, because of poor source quality. If a system will not be able to comply with an MCL after installation and/or use of the "best technology, treatment techniques, or other means which the Administrator finds to be generally available," taking costs into consideration, the system may apply for a variance. Section 1415(a)(1)(A). 42 U.S.C. 300g-4(a)(1)(A). A variance, if granted, would insulate the system not in compliance from enforcement actions for exceeding the

MCL. The system, however, would be required in connection with a variance to install and/or use "generally available" treatment methods that would reduce the levels of a particular contaminant. Thus, the treatment method should be in-place to demonstrate that non-compliance is attributable to poor source water quality, thereby entitling the system to a variance. However, this finding may be made prior to the methods actually being operational. The important fact is that the "available and effective" methods be installed in order to reduce contaminant levels. In addition, pursuant to Section 1414(c)(2), 42 U.S.C. 300g-3(c)(2) and 300g-4(a)(1)(A), any system that receives a variance will be put on a compliance schedule and must give notice of the variance to its consumers.

In addition to the primary regulations, the SDWA requires EPA to set Secondary Drinking Water Regulations which are to protect the public welfare. The secondary regulations may apply to any contaminant in drinking water that may adversely affect the odor or appearance of the water. Section 1401(2) 42 U.S.C. 300g-1(c). Secondary maximum contaminant levels (SMCLs) and monitoring requirements have been established (40 CFR Part 143, 41 FR 42195, July 19, 1979).

In addition to the regulatory mandates, the SDWA provides authorities for ensuring the safety of the nation's drinking water in a non-regulatory context. Section 1442(a)(2)(B) authorizes EPA to provide technical assistance to States and publicly owned water systems in response to and alleviation of any emergency situation which the Administrator determines to be a substantial danger to public health. In the absence of appropriate State or local action, Section 1431 authorizes EPA to take such actions as the Administrator deems necessary to protect public health from a contaminant that may present an imminent and substantial endangerment to the health of persons.

III. Regulatory Framework

The issuance of Revised Primary Drinking Water Regulations is the third step in the evolution of the primary drinking water regulations mandated by the SDWA.

In the *first step*, the National Interim Primary Drinking Water Regulations were promulgated on December 24, 1975, with an effective date of June 24, 1977. Amendments were issued in 1976, 1979 and 1980. Maximum contaminant levels (MCLs) and monitoring and reporting requirements were set for numerous

microbiological, inorganic, organic, and radio-nuclide contaminants. At the direction of the Congress, EPA based the Interim Regulations in large part on the 1962 U.S. Public Health Service (PHS) Standards for drinking water which in turn were derived from previous standards dating as far back as 1915 for the microbiological standards and the 1940's for the MCLs for some of the inorganic chemicals.

As the *second step*, Section 1412(e) of the SDWA directed EPA to arrange for the National Academy of Sciences (NAS) to conduct a study to assess the health effects of contaminants in drinking water and to provide proposed RMCLs at levels at which there were "no known or anticipated effects on the health of persons." The NAS submitted its initial report, *Drinking Water and Health*, to EPA in 1977 which was published in the Federal Register for public comment; additional reports were submitted in 1980 and 1982. While Congress envisioned that NAS would provide proposed RMCLs in the report, the NAS stated essentially that it would do toxicological assessments of contaminants in drinking water but developing proposed RMCLs was not an NAS responsibility but an EPA regulatory function. In the words of the Academy, "determining safe levels to protect the health of persons' drinking water containing contaminants requires consideration of other factors in addition to the harmful properties of the contaminants" (John S. Coleman, Executive Officer, NAS, Feb. 20, 1975). The 1977 and subsequent NAS reports have provided EPA with toxicological assessments of contaminants in drinking water. Using this information and data from other scientific sources, EPA will develop and publish RMCLs for some of these substances.

As the *third step*, Section 1412(b)(1)(B) and 1412(b)(2) provided that EPA must propose and promulgate RMCLs and National Revised Primary Drinking Water Regulations (NPDWR) that would include MCLs and monitoring and reporting requirements for those contaminants that may have an adverse effect on human health.

Regulatory Development Approach

Development of the NPDWR will be accomplished in four phases:

- Phase I Volatile Synthetic Organic Chemicals,
- Phase II Synthetic Organic Chemicals, Inorganic Chemicals and Microbiological Contaminants
- Phase III Radionuclides
- Phase IV Disinfectant By-Products including Trihalomethanes

In general the approach for all four phases will be similar:

- Initially an ANPRM will be published followed by a comment period and a public meeting. Public technical workshops will also be held. The workshops provide an opportunity for EPA to present the issues that must be addressed in development of the regulations and to receive information on scientific and technical matters as well as receive comments on regulatory approaches.

- RMCLs will then be proposed followed by a public comment period and a public hearing(s).

- RMCLs will then be promulgated and proposals published for MCLs, monitoring and reporting, and other requirements followed by a public comment period and a public hearing(s). Technologies will be identified that were used as the basis of determining the MCLs; in addition, generally available treatment technologies (GAT) will be identified for use in the issuance of variances.

- The MCLs, monitoring and reporting, and other requirements including GAT will then be promulgated.

An ANPRM for Phase I (volatile synthetic organic chemicals) was issued on March 4, 1982 (47 FR 9350), and a public meeting was held in Washington, D.C., on April 28, 1982. In addition, four public technical workshops were conducted across the country on volatile synthetic organic chemicals (VOCs) in drinking water.

Today's ANPRM addresses Phases II and III and initiates the regulatory assessment of the Interim Regulations. The proposed revised regulations for radionuclides (Phase III) will follow the Phase II proposal by approximately one year. In addition, within Phase II, regulations for fluoride will be proposed separately in response to a petition filed by the State of South Carolina (see 46 FR 58345, December 1, 1981).

While this ANPRM initiates the formal rulemaking process for development of Phase II and III of the NPDWR, data collection and developmental activities have been ongoing for the past several years. As part of these efforts, two public workshops have been conducted; a public workshop on the microbiological standards, was held on December 4-6, 1981, and a workshop on the radionuclide standards was held on May 24-26, 1983. In addition, four public workshops will be conducted at several locations across the country during the comment period for this ANPRM.

Phase IV of the NPDWR will address trihalomethanes (THMs) and other

disinfection-related contaminant issues, since regulations for these substances have been in effect only since 1979 and this has not yet provided sufficient time for a re-evaluation and revision to be feasible. It is expected that by 1985 additional data on implementation with the THM regulations and other research experience will be available including new data on the nature and toxicology of alternate disinfectants and their by-products; at that time EPA will review those regulations and determine appropriate revisions.

During the development of the NPDWR, existing draft Health Advisories (HAs) will be revised if necessary and additional advisories will be prepared and issued on other substances for which no regulations currently exist. Health Advisories provide scientific guidance on the health effects of chemicals detected in drinking water supplies and are developed following the state-of-the-art concepts in toxicology. HAs receive scientific peer review as well as consideration by EPA's Science Advisory Board as needed. The HAs specify non-carcinogenic risk for transient exposures and suggest a level of a contaminant in drinking water at which adverse health effects would not be anticipated. A margin of safety is factored in so as to protect the more sensitive members of the general population. For contaminants considered to be suspected carcinogens, the carcinogenic risk rates are also provided with no specific level recommended. The Health Advisory Program was developed by EPA's Office of Drinking Water in response to the growing concern over the chemical contamination of drinking water supplies across the country. As chemicals are discovered in drinking water, decisions must be made by federal, State and community officials as to the suitability of such contaminated water for human consumption. HAs are offered as advice to assist those dealing with specific contamination situations.

Pursuant to Executive Order 12291 (46 FR 13193, February 19, 1981), EPA will prepare a regulatory impact analysis (RIA) prior to proposal if the Agency determines that the NPDWR are considered "major rules".

In addition, pursuant to the Regulatory Flexibility Act, an analysis of the impacts on small entities will be conducted prior to proposal of NPDWR if the Agency determines such regulations are likely to have a significant economic impact on a substantial number of small entities.

This analysis would also be available for public comment.

The development process described above is intended to provide the greatest opportunity for all interested parties including States, communities, health and science experts, public interest groups, water engineering and treatment officials and citizens to participate and advise EPA on the proper direction to be taken.

III. NPDWR: Approaches Under Consideration

Development of the NPDWR will involve a comprehensive assessment of contaminants in drinking water including re-examination of the requirements and implementation experiences of the Interim Regulations. Under the requirements and definitions of the SDWA, the basic questions being considered in the efforts include:

- For which contaminants should regulations be set?
 - What levels for the RMCLs and MCLs would be appropriate?
 - What monitoring and reporting requirements would be appropriate?
- Responses to these questions necessitate extensive data collection and analyses in such areas as the occurrence of contaminants in drinking water, potential health effects, the availability of analytical methods, the availability and performance of treatment technologies, and the costs of treatment and monitoring.

In addition, valuable operational experience has been gained from implementation of the Interim Regulations and, based upon this experience, several adjustments for the NPDWR are under consideration. The implementation experience can generally be classified into the following:

- Findings regarding quality of drinking water;
- Compliance problems with Interim Regulations;
- Apparent inefficiencies in some aspects of the monitoring requirements under the Interim Regulations.

Interim Regulations Implementation Experience

The Interim Regulations include MCLs and monitoring and reporting requirements for ten organic compounds (i.e., six pesticides and total trihalomethanes), ten inorganic compounds, microbial contaminants (coliforms and turbidity), and radionuclides. Monitoring and reporting requirements are also included for sodium and corrosivity.

The regulations apply to some 60,000 community water supply systems and

163,000 non-community systems. Most of these systems are small and use ground water as their source; 90 percent of the systems serve 10 percent of the population. Approximately two-thirds (i.e., over 38,000 systems) of all community systems serve fewer than 500 people.

Status of Drinking Water Quality

Despite improvements in disinfection and other types of water treatment, outbreaks of waterborne disease still occur, particularly in smaller communities. From 1971-80, there were 315 reported outbreaks of waterborne disease involving almost 78,000 cases; 50 outbreaks and 20,000 cases occurred in 1980 alone. At least two deaths were involved. Major causes of outbreaks in community water systems were contamination of the distribution system and treatment deficiencies, such as inadequate filtration and interruption of disinfection. Specific causes of other outbreaks could not be determined. In non-community water systems, contamination of ground water used without treatment or with treatment deficiencies (usually interruption of or inadequate disinfection) was responsible for most outbreaks and cases.

Many outbreaks, probably the great majority, are not reported to the Centers for Disease Control (CDC), which keeps records on the occurrence of reportable diseases, because few waterborne diseases are required to be reported and also because of difficulties in identifying the etiology of these occurrences. In Colorado, a current pilot effort to improve the outbreak reporting system indicated that perhaps only about one-fifth of the actual outbreaks were being recognized and reported. As recognition of waterborne illness has improved, the trend in the reported, although not necessarily the actual number, outbreaks and cases has increased.

Monitoring for inorganic chemicals has shown that 1500-3000 systems have levels above the MCLs for certain of the contaminants. These inorganics are mostly a problem in ground waters and removal of inorganic chemicals can be difficult and relatively expensive on a per capital basis for small public water systems. Problems continue primarily with compliance with the MCLs for arsenic, barium, lead (from pipe or solder corrosion), fluoride and to an increasing degree, nitrate.

In addition to the traditional contaminants of mineral origin, the presence of synthetic organic chemicals of industrial origin (including pesticides) has been detected with increasing frequency, especially in ground water

sources. Some surface waters are being contaminated with industrial and municipal wastes although in many cases, application of pollution controls has apparently improved surface water quality in recent years. While the six pesticides in the Interim Regulations have seldom been found in drinking water supplies, contamination of surface water by other pesticides during runoff can be a significant problem in certain areas; this has been shown by recent studies in Ohio in which finished drinking water levels of locally used agricultural pesticides paralleled seasonal use.

Radionuclide contamination in drinking water can be due to natural or man-made radioactivity. Monitoring for man-made radioactivity currently applies only to surface water supplies serving populations larger than 100,000. There have been no violations reported of the MCL for man-made radioactivity. The regulations for radium apply to all public water systems and monitoring has shown that approximately 500 public water supplies exceed the MCL for radium (a natural contaminant). Uranium and radon, though not included in current regulations, occur with comparable frequency.

While contamination of source waters has traditionally been the primary concern, attention must also be given to the impact of treatment and distribution on the quality of water delivered to the consumer. For example, chlorine used in water treatment generates trihalomethanes and other organic chemicals; other treatment chemicals may contribute traces of contaminants from impurities or residues. The materials used to construct and preserve the conduits and storage facilities for drinking water as well as plumbing in the home can also contribute contaminants such as metals and organic residues from surface coatings. Bacterial growths in distribution systems are a familiar characteristic especially of older systems or where water is inadequately treated.

Compliance Problems With the Interim Regulations. During fiscal year 1982, over 70,000 violations of the Interim Regulations were recorded by 20,000 of the community water systems. Most of these violations were for monitoring and reporting (84%) but it is estimated that over 9,000 systems require improved facilities to meet drinking water standards. Compliance records for non-community systems were incomplete but do indicate that monitoring is generally not being conducted on schedule.

Compliance with the Interim Regulations has been a problem mostly for small systems. For example:

- The microbiological requirements were not met by many of the smaller systems (serving less than 3,300 people) in 1982; the data show that 10 percent of the systems violated the MCL and over 25 percent violated the monitoring requirements.

- Of the large systems (serving over 100,000 people), 4 percent exceeded an MCL, and 3.7 percent failed to monitor adequately.

Although most small water systems deliver good quality water, when a problem does occur, a small community is generally least able to cope with it. The cost of treatment is sometimes beyond the economic capability of the small system, and the skilled manpower necessary to operate treatment facilities is even more difficult to obtain.

For those systems not in compliance with various MCLs, in particular some of the MCLs for inorganic chemicals, the problems are generally because of the costs and feasibility of installing and operating treatment facilities. However, this compliance problem goes beyond the question of costs and includes the issue of potential health effects especially for naturally occurring (particularly in ground water supplies) contaminants like radium, selenium, barium, and fluoride. Some of these systems, many of which are small, remain unconvinced that the net benefits of contaminant reduction are worth their costs.

Monitoring Experience. The SDWA assigns to EPA the responsibility for developing national primary drinking water regulations which contain the minimum national requirements for the assurance of safe drinking water. States which have primary enforcement responsibility must adopt regulations which are no less stringent than the national regulations. State regulations may contain more detailed monitoring requirements or more specific criteria and procedures than do the national regulations.

The Interim Regulations require monitoring to assess compliance with the MCLs at set frequencies for certain contaminants; for example, monitoring for inorganic compounds must be conducted at least once per year or once per three years for supplies using surface or ground water sources, respectively. While monitoring once a year or every three years does not seem to be overly demanding, this can be a burden upon small system, and upon those States that conduct monitoring for certain of the systems (e.g., small

systems) within their boundaries. States have reported that certain of these inorganic compounds have not been detected at significant levels in the drinking water in many systems and the probability of future contamination is very slight. Monitoring has shown that little change in concentrations occurs over time for certain contaminants, primarily ground water contaminants. In addition, some contaminants such as the six pesticides in the Interim Regulations have been found only rarely since compliance monitoring requirements went into effect.

These are areas which appear to warrant significant modification in development of the NPDWR in order that public water system and State resources will be used more efficiently to be more reflective of local or regional conditions.

Approaches Under Consideration

As outlined above, several problems with the Interim Regulations and their implementation need to be addressed in the developmental efforts leading to the NPDWR. The regulatory approaches currently under consideration to address these problems are discussed below.

Compliance by (Small) Systems

The NPDWR would identify technologies representative of generally available treatments described in the SDWA. The approach would be similar to that promulgated for the trihalomethane regulations (40 CFR Part 142, 48 FR 8406, February 28, 1983). These would assist States in issuing variances.

Variances may be granted when a system, "because of characteristics of the raw water sources which are reasonably available to the systems, cannot meet the requirements . . . despite application of the best technology, treatment techniques, or other means, which the Administrator finds are generally available (taking costs into consideration)." (Section 1415(a)(1)(A)). Variances do not have a fixed date in the law for the system to come into compliance but the system must be put on a compliance schedule.

Generally available technology (GAT) would be defined for each regulated contaminant, taking costs into consideration and possibly categorizing by system characteristics such as size or water source. States would evaluate each case on a site-specific basis to determine if the identified GAT was appropriate and effective for that system. In addition to central treatment alternatives, use of bottled water and point-of-use treatment devices are being

considered as means of reaching compliance with the NPDWR.

In addition to identification of GAT and the associated costs of contaminant reduction, EPA will provide for public comment comprehensive health criteria documents for each of the contaminants to be included in the NPDWR. These documents will contain detailed assessments of all available information and will fulfill the mandates of evaluating the risks of contaminants in drinking water and the design of the regulatory framework for them.

Three Tiered Approach

A three tiered approach has been developed for determining whether and in what manner to regulate specific contaminants. This approach was discussed in the public meetings on the Safe Drinking Water Act in February 1982 and by the National Drinking Water Advisory Council in March 1982 and was widely supported.

Drinking water contaminants would be divided into three categories for regulatory purposes:

Category I.—Those which occur with sufficient frequency and which are of sufficient concern to warrant national regulation (MCLs) and consistent monitoring and reporting.

Category II.—Those which are of sufficient concern to warrant national regulation (MCLs) but which occur at limited frequency, justifying flexible minimum monitoring requirements to be applied by State authorities.

Category III.—Those which would not warrant development of a regulation but for which non-regulatory health guidance could be provided to States or water systems.

Category I Contaminants

Certain contaminants such as coliforms, turbidity and some inorganic and organic chemicals are widely detected in drinking water supplies and pose serious health risks when MCLs are exceeded. Without consistent or frequent oversight, these MCLs have a high potential for being exceeded. Such contaminants warrant national regulations with fixed minimum requirements, including regular monitoring requirements. States would be required to adopt and apply those regulations as written; States could produce more stringent requirements as needed.

Category II Contaminants

The occurrence of many drinking water contaminants is sometimes predictable based upon geological conditions, source type, and historical

record. Contaminants such as natural radionuclides, certain pesticides and some inorganics such as barium may well be predictable; thus, repeated monitoring according to the present formula may use resources for non-productive monitoring, once compliance status has been determined and source conditions are stabilized.

Cases such as these appear to warrant conferring the maximum discretion with States so that activities can be tailored to regional conditions. Thus, although an MCL identical to Category I would be developed by EPA, and compliance with the MCL would be required in all cases, States could be provided flexibility in establishing monitoring requirements within stated criteria.

In addition, some contaminants such as nitrate may be of concern to a definable portion of the population, e.g., young children below a certain age. It may be possible to provide flexibility to States in applying a standard when the high risk population is not exposed.

Category III Contaminants

Over the past few years, particularly in connection with contamination of ground waters by organic solvents and pesticides, there has been a need for rapid determination of "safe" or "acceptable" levels of these contaminants in drinking water for short periods of consumption. Advice is often needed in a very short time to determine whether immediate control is necessary. In many cases the need has been met by issuing Health Advisories which provide information on the health effects of unregulated contaminants so that users of the water in question can be assisted in determining what action to take. Health Advisories are developed for various lengths of exposure, from one day to longer term (up to one to two years), depending on the availability of data.

While some of the contaminants for which Health Advisories have been prepared may occur with sufficient frequency and at high enough concentrations to be considered for NPDWR, there undoubtedly will be a large number of contaminants which do not merit that level of regulation. In these latter cases, EPA would not establish NPDWRs but provide *non-regulatory advisories* when requested by a State or public water system. These advisories would be produced through a process that would integrate activities in the various EPA program offices including the Office of Drinking Water and the Office of Pesticide Programs. Development of the advisories would include intensive scientific and technical evaluation of available data coupled

with peer review by leading toxicologists.

IV. NPDWR: Regulatory Assessments

This section provides background information on the issues and alternatives that must be considered in determining the appropriate levels for RMCLs and MCLs and the specific monitoring/reporting requirements. Public comments and information are requested that will assist EPA in making these determinations.

RMCLs

RMCLs are to be set at levels at which:

No known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety.

For those toxic compounds for which there may be no threshold (e.g., carcinogens), the House Report 93-1185 suggested that the "no effect" level should be zero.

RMCLs: Scientific Approaches. When appropriate data are available from human epidemiology or animal studies, determination of the "no effect" level for RMCL purposes for toxic agents not considered to have carcinogenic potential is a relatively well-accepted procedure. In classical toxicology, "no effect" levels for chronic or lifetime periods of exposure are referred to commonly as ADIs or Acceptable Daily Intakes. These ADIs are defined as exposure levels which would be without risk to humans when received daily over a lifetime. For non-carcinogenic endpoints of toxicity, it is assumed that an organism can tolerate and detoxify some amount of a toxic agent without ill effect up to a certain dose or threshold. A threshold is defined as that dose of a given substance which is required to elicit a measurable biologic response. As the threshold is exceeded, the extent of the response will be a function of the dose applied and the length of time exposed.

The intent of a toxicological analysis performed as part of the regulatory development process is to identify the highest no-observed-adverse-effect-level (NOAEL) based upon assessment of human or animal data (usually from animal experiments). To determine the ADI or RMCL "no effect" level, the NOAEL is divided by appropriate "uncertainty" or "safety" factors. This process accommodates for the extrapolation of animal data to the human, for the existence of weak or insufficient data and for differences in

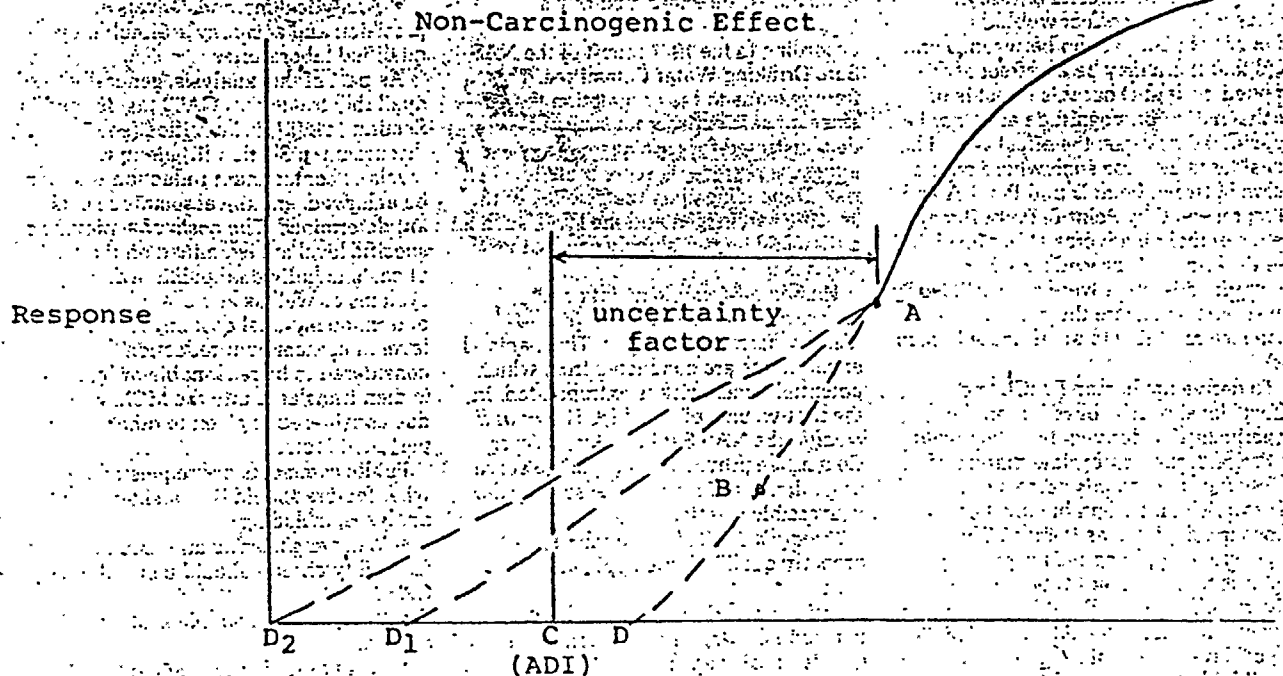
human sensitivity to toxic agents, among other factors. General guidelines were provided by the NAS Safe Drinking Water Committee which state that an uncertainty factor of 10 is used if there exist valid experimental results via

ingestion in humans; an uncertainty factor of 100 is used if there exist valid experimental results on long-term feeding studies on experimental animals; and an uncertainty factor of 1000 is used if there exist inadequate

animal data. Additional factors also may be used if the circumstance dictate it.

The process by which an ADI or RMCL "no effect" level for humans is established is illustrated in Figure 1.

Figure 1



Dose

A: NOAEL (experimentally derived)

B: NOAEL (theoretically possible)

C: ADI or RMCL "no effect" level

D: Presumed threshold for any effect (not adverse)

D₁: Another possible presumed threshold for any effect (not adverse)

D₂: Non-threshold end point of toxicity

Figure 1 shows the lower end of a typical, sigmoid-shaped dose-response curve as might be generated experimentally for a non-carcinogenic end-point of toxicity believed to have a threshold. The solid line represents the curve as experimentally-determined. Point A represents the highest NOAEL determined during the experiment. Point D represents the threshold dose at or above which any effect would be elicited. The distinction between D and A is that there may be an effect of the applied dose at D but this effect is of such a nature or magnitude as to not be considered adverse; the effect would be considered adverse somewhere on the curve between Point D and Point A and is represented by Point B. Point B may be the actual no adverse effect level, if the experimental procedure which determined Point A were not sufficiently sensitive to measure the precise response relating to an ultimate human risk.

To derive the human RMCL "no effect" level or ADI based upon the experimentally derived data displayed in Figure 1, the appropriate margin of safety (i.e., uncertainty factor) is applied to establish an acceptable level of exposure, depicted as Point C. The objective of applying the uncertainty factor is to make Point C below the no adverse effect level, Point B. Thus, Point C would represent the ADI or RMCL "no effect" level with a margin of safety. It is possible that the actual dose response curve would result in Point D, in which case the ADI or RMCL "no effect" level (i.e., Point C) might not be below the presumed threshold for any effect.

There is suggestive scientific evidence available to postulate that thresholds do exist for noncarcinogenic end-points of toxicity. In the absence of irrefutable evidence, however, it remains theoretically possible that one or more noncarcinogenic end-points may not have a demonstrable threshold. The dose-response curve for this case is depicted as the dashed line from Point A to the origin or D₀. D₀ represents the threshold dose and the RMCL "no effect" level in this case would thus be zero.

Determination of RMCL "no effect" levels for substances which may possess carcinogenic potential is a two-phase process. In the first phase, the toxicological data base for non-carcinogenic end-points of toxicity is evaluated in the same manner as described above for "noncarcinogens". In the second phase, assessment is made of the evidence which measures directly the carcinogenic potential (e.g., long-term bioassays in rodents) as well

as evidence which provides indirect support (e.g., mutagenicity and other short-term test results). This process is difficult since the production of cancer is a multistage event, determined by a multiplicity of mechanisms, the nature of which remain, for the most part, hypothesized rather than identified.

To date, scientists have been unable to demonstrate experimentally a threshold of effect for "carcinogens," according to the 1977 report of the NAS Safe Drinking Water Committee. This finding leads to the assumption that since no safe exposure dose can be demonstrated for carcinogens, any exposure represents some finite level of risk. Depending upon the potency of the specific carcinogen and the level, such a risk would be vanishingly small at very low doses.

Human epidemiology data are extremely limited in their ability to identify carcinogenic risks. Thus, animal experiments are conducted from which potential human risk is extrapolated. In the first volume of *Drinking Water and Health*, the NAS Safe Drinking Water Committee provided principles to serve as guidance to EPA when assessing the irreversible effects.

Principle 1: Effects in animals, properly qualified, are applicable to man.

Principle 2: Methods do not now exist to establish a threshold for long term effects of toxic agents.

Principle 3: The exposure of experimental animals to toxic agents in high doses is a necessary and valid method of discovering possible carcinogenic hazards in man.

Principle 4: Material should be assessed in terms of human risk, rather than "safe" or "unsafe".

Many of the substances treated in this ANPRM are not considered to be carcinogens. The issue of RMCLs and MCLs for carcinogens was discussed in the ANPRM for VOCs (47 FR 9350) and will be discussed at length in the forthcoming proposed RMCLs for VOCs. Public comments are requested on the establishment of RMCLs including the methodology for assessing non-carcinogenic toxic effects and the use of the ADI as the RMCL. In addition, public comments are requested on the method to be used to determine the level that should be set for RMCLs for carcinogens.

MCLs

Section 1412(b)(3) requires that MCLs be set "as close to" the RMCLs "as is feasible". Feasible means "with the use of the best technology, treatment and other means, which the Administrator

finds are generally available (taking costs into consideration)."

Thus, MCLs are based upon a balancing of numerous factors including:

- Potential health risks;
- Performance of available treatment technologies;
- Feasibility and costs of treatment; and
- Analytical methods: levels of precision and accuracy attainable by qualified laboratories

As part of this analysis, generally available treatment (GAT) (as defined in Section 1412(b)) is identified (see discussion in Section III) along with levels of contaminant reduction that can be achieved, and the associated costs are determined. The costs of achieving a specific level are examined on the basis of costs to individual public water systems as well as aggregated to determine national cost impacts. The level of contaminant reduction considered to be reasonable or feasible is then translated into the MCL, with due consideration given to other pertinent factors.

Public comments are requested on what factors should be considered in the analyses, including:

- What engineering and technical feasibility criteria should be used to set GAT?
- What is a reasonable cost for the consumer?
- What other factors should be considered as pertinent in determination of the levels for MCLs?

Monitoring/Reporting

The objective of monitoring is to assure compliance with the MCLs and, of course, to indicate the quality of the drinking water. Monitoring requirements will vary depending upon which contaminants and into which Category (i.e., of the three tiered approach discussed previously) the contaminants have been placed. The primary considerations include:

- Frequency of sampling;
- Number of samples;
- Locations of samples: in the distribution system, at the plant, or each well;
- Availability of reliable analytical methods;
- Precision/accuracy of analytical methods;
- Availability of qualified laboratories;
- Costs of monitoring; and
- Distinctions between surface and ground water sources.

Public comment is requested on the above factors and how they would apply to the contaminants under

consideration. In addition assistance is requested on factors that should be used in determining reduced (or increased) monitoring requirements, such as quality of the water supply based upon sampling or a sanitary survey, proximity to hazardous waste sites, or proximity to potential contamination sources such as upstream industrial pollutant discharges or pesticide usage.

Public comment is also requested on appropriate reporting requirements for public water systems such that an efficient procedure is followed for determining compliance while minimizing paperwork. Current requirements are (1) to report any positive samples above MCLs (after appropriate check or follow-up sampling) within 48 hours and (2) to report routine monitoring data either (a) 10 days following the month in which the result is received or (b) within the first 10 days following the end of a monitoring period.

V. NPDWR: Specific Considerations

Discussed below are specific contaminants which are being considered for inclusion in the NPDWR. For each contaminant EPA is assessing the current MCL and monitoring requirements and requesting assistance in determining answers to the following:

- For which contaminants are RMCLs and MCLs appropriate under the SDWA requirements? In addition to those discussed below, which additional substances should be considered?

- What additional data are available to support the determination of appropriate RMCLs and MCLs?

- Given the toxicology and occurrence characteristics, what monitoring and reporting requirements would be appropriate in each case?

Microbiology and Turbidity

The microbiological aspect of drinking water quality has been the subject of standards since 1914. The Interim Regulations, as do most of the earlier standards, rely on the measurement of total coliforms and turbidity as indicators of fecal pollution and water treatment efficiency, respectively. Specific MCL requirements of the Interim Regulations, simply stated, are the following:

Total coliforms..... 1 per 100 ml monthly average,
4 per 100 ml single sample.
Turbidity..... 1 Turbidity Unit (TU) (up to 5 TU).

Monitoring requirements for coliforms, depending upon the size of system, range from 500 samples per month for systems serving more than 4.7 million persons to one sample per month for

systems serving 25 to 1,000 persons. Turbidity monitoring is required daily for systems using surface water supplies.

Although coliforms are not usually pathogenic, their presence in water implies that human microbial pathogens may be present. The concept of coliform measurements as a practical indicator of microbiological quality is universally accepted, but there have been numerous other parameters suggested as means for judging the microbiological quality of drinking water. While the coliform measurement still appears to be the preferred parameter, as confirmed by recent symposia and workshops, there appears to be a need to reconsider and update the regulatory framework. The current regulations for microbiological contaminants are admittedly complicated; there are two analytical procedures, the sampling frequency is variable, the volume of sample to be examined is variable, and there are MCLs for single samples and for monthly averages; in addition the concept of "check" samples is frequently misunderstood, in large part because the term "check samples" is not an accurate description of the samples or their purpose. EPA's goal for the NPDWR is to streamline, to the extent feasible, the complex aspects of existing microbiological regulations and to assure that meeting the regulations will assure safe drinking water. In addition to coliforms and turbidity, consideration is being given to the following drinking water microbiology issues in the NPDWR in light of recommendations from the Drinking Water Microbiology Workshop.

Giardia lamblia

Viruses

Standard plate count

Legionella

Filtration treatment for surface water Disinfection requirement

As noted above, development of NPDWR will not only involve addressing current requirements in the Interim Regulations but will also evaluate new controls for such contaminants as *Giardia lamblia* and viruses. *Giardia lamblia* is a protozoan which is a human intestinal parasite and is the cause of giardiasis, a disease which can be mild or extremely debilitating. *Giardia* infections can be acquired by ingesting viable cysts from food or water. Several outbreaks of giardiasis have been traced to municipal water supplies, and humans and both wild and domestic animals have been implicated as hosts. Between 1972 and 1980 there were 38 reported waterborne

outbreaks of giardiasis with about 20,000 reported cases.

At the present time, there is no simple and reliable method for assaying *Giardia* cysts in water samples.

Microscopic methods for detection and enumeration are tedious and require skill and patience on the part of the examiner.

Giardia cysts are relatively resistant to chloride, but preliminary evidence indicates that cysts can be killed at warmer temperatures (e.g., 20° C) with 1.5 mg/l chlorine for 10 minutes. Filtration, whether through diatomaceous earth or granular media, has been shown to be effective for removing cysts of *Giardia* and another pathogenic protozoan, *Entamoeba histolytica*.

Viruses have been implicated in numerous outbreaks of waterborne disease. Between 1978 and 1981, 12 waterborne outbreaks involving about 5,000 cases were attributed to viruses. Undoubtedly, the reported number of outbreaks is substantially lower than actual numbers. Moreover, in about half the outbreaks of waterborne disease, the causative agent has not been found. There is growing suspicion that most of these are due to viruses. These organisms are generally more resistant to disinfection than coliforms, and thus may be present in drinking waters meeting current regulations. Because of these factors, viruses are being considered for inclusion in the NPDWR.

Some of the information needed to develop RMCLs and MCLs for *Giardia* and/or viruses would include dose-response data, which are currently limited, and suitable recovery and assay methods. Alternatives under consideration include:

1. Because analytical methods do not appear to be "economically or technically feasible" (Section 1401(1)(c)(ii)) and because conventional drinking water treatment technologies are effective in removing *Giardia* and/or viruses, one option would be to establish a treatment technique requirement consisting of filtration and disinfection for surface water systems.

2. On the other hand, perhaps a hybrid approach could be considered where RMCLs and MCLs and a treatment technique requirement would be set; States would then be able to allow installation and operation of appropriate technologies in lieu of expensive monitoring that would be associated with MCL compliance requirements.

Legionella is being considered for inclusion in the NPDWR. This bacteria is responsible for causing Legionnaires Disease and Pontiac Fever and many

consideration. In addition assistance is requested on factors that should be used in determining reduced (or increased) monitoring requirements, such as quality of the water supply based upon sampling or a sanitary survey, proximity to hazardous waste sites, or proximity to potential contamination sources such as upstream industrial pollutant discharges or pesticide usage.

Public comment is also requested on appropriate reporting requirements for public water systems such that an efficient procedure is followed for determining compliance while minimizing paperwork. Current requirements are (1) to report any positive samples above MCLs (after appropriate check or follow-up sampling) within 48 hours and (2) to report routine monitoring data either (a) 10 days following the month in which the result is received or (b) within the first 10 days following the end of a monitoring period.

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systems serving 25 to 1,000 persons. Turbidity monitoring is required daily for systems using surface water supplies.

Although coliforms are not usually pathogenic, their presence in water implies that human microbial pathogens may be present. The concept of coliform measurements as a practical indicator of microbiological quality is universally accepted, but there have been numerous other parameters suggested as means for judging the microbiological quality of drinking water. While the coliform measurement still appears to be the preferred parameter, as confirmed by recent symposia and workshops, there appears to be a need to reconsider and update the regulatory framework. The current regulations for microbiological contaminants are admittedly complicated; there are two analytical procedures, the sampling frequency is variable, the volume of sample to be examined is variable, and there are MCLs for single samples and for monthly averages; in addition the concept of "check" samples is frequently misunderstood, in large part because the term "check samples" is not an accurate description of the samples or their purpose. EPA's goal for the NPDWR is to streamline, to the extent feasible, the complex aspects of existing microbiological regulations and to assure that meeting the regulations will assure safe drinking water. In addition to coliforms and turbidity, consideration is being given to the following drinking water microbiology issues in the NPDWR in light of recommendations from the Drinking Water Microbiology Workshop.

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outbreaks of giardiasis with about 20,000 reported cases.

At the present time, there is no simple and reliable method for assaying *Giardia* cysts in water samples. Microscopic methods for detection and enumeration are tedious and require skill and patience on the part of the examiner.

Giardia cysts are relatively resistant to chloride, but preliminary evidence indicates that cysts can be killed at warmer temperatures (e.g., 20° C) with 1.5 mg/l chlorine for 10 minutes. Filtration, whether through diatomaceous earth or granular media, has been shown to be effective for removing cysts of *Giardia* and another pathogenic protozoan, *Entamoeba histolytica*.

Viruses have been implicated in numerous outbreaks of waterborne disease. Between 1978 and 1981, 2 waterborne outbreaks involving about 5,000 cases were attributed to viruses. Undoubtedly, the reported number of outbreaks is substantially lower than actual numbers. Moreover, in about half the outbreaks of waterborne disease, the causative agent has not been found. There is growing suspicion that most of these are due to viruses. These organisms are generally more resistant to disinfection than coliforms, and thus may be present in drinking waters meeting current regulations. Because of these factors, viruses are being considered for inclusion in the NPDWR.

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1. Because analytical methods do not appear to be "economically or technically feasible" (Section 1401(1)(c)(ii)) and because conventional drinking water treatment technologies are effective in removing *Giardia* and/or viruses, one option would be to establish a treatment technique requirement consisting of filtration and disinfection for surface water systems.

2. On the other hand, perhaps a hybrid approach could be considered where RMCLs and MCLs and a treatment technique requirement would be set; States would then be able to allow installation and operation of appropriate technologies in lieu of expensive monitoring that would be associated with MCL compliance requirements.

Legionella is being considered for inclusion in the NPDWR. This bacteria is responsible for causing Legionnaires Disease and Pontiac Fever and many

of the currently existing population-frequency relationship; (2) five samples/month and use of the total length of pipes in the distribution system as a basis for frequency of sampling. The minimum number of samples for the largest category of systems should remain 500/month.

- SPC levels should be monitored at the same frequency as coliforms, at least initially until a data base is established.

- Monitoring for turbidity should be increased to one each eight hours unless continuous monitoring is provided. The average of the three analyses should be reported as the daily value or, with continuous monitoring, the average of the graphical record should be used.

- Some monitoring for specific pathogens which are not directly related to fecal indicator counts in finished water were also recommended. See the "Proceedings" document for more detail on these recommendations.

- The existing sampling regulations for non-community water systems (NCWS) (§ 141.21 (c)) are adequate for small systems. It was recommended that NCWS serving more than 500 persons per day be required to sample at the same frequency as community water systems of similar size.

- All systems using surface water, except small systems, should provide continuous monitoring of disinfectant residual at an entry point to the distribution system. Systems serving more than 10,000 persons should monitor disinfectant residual in the distribution system at the same frequency as bacteriological sampling (suggested as guidance).

- *Analytical Methods and Sample Handling.* The following recommendations were made relative to analytical methods and sampling:

- Participants concluded that the fermentation tube (FT) and membrane filtration (MF) procedures are appropriate for the enumeration of total coliforms; participants recognized that significant underestimates of coliform number occur with both procedures, and suggested specific requirements be included in the NPDWR to attempt to minimize this problem. See the "Proceeding" for more details.

- For SPC analysis, any of the procedures listed in *Standard Methods* or equivalent, using 48-hour incubation at 35°C, are acceptable.

- It was recommended that the current 30-hour maximum sample transport time be retained with some modifications. The regulation should specify that samples shall be analyzed as soon as possible, but no later than 30 hours after collection. Later samples should not be discarded

indiscriminantly, but based on the specific situation. Some participants recommended a 30-hour maximum limit on unrefrigerated samples and 54 hours on refrigerated ones.

- Some participants suggested that coliforms be defined as any rod-shaped, gram-negative, facultative anaerobe which ferments lactose in 48 hours at 35°C. This would include the genus *Aeromonas*.

- *Source Water, Treatment and Distribution System Requirements.* On the subject of treatment guidelines and requirements, the following conclusions emerged.

- The issue of establishing a water quality index, relating raw water quality and treatment requirements, was discussed. It was felt that sufficient data on a variety of parameters do not exist to allow establishment of such an index. Instead, minimum treatment requirements for water supply sources were recommended.

- Minimum treatment for ground water sources should be disinfection.

- All surface water sources should be pretreated by such processes as coagulation, sedimentation and filtration or their equivalent prior to disinfection, unless it can be shown on the basis of a sanitary survey that such treatment is not necessary. One reason for this is for control of *Giardia* cysts.

- Some participants felt that minimum treatment requirements for small systems should be evaluated on a case-by-case basis but this assumed a history of compliance and that increased monitoring and use of SPC will be done.

- All new finished water reservoirs should be required to have a cover. Non-mandatory policy should be developed for covering existing finished water reservoirs.

Comments are solicited on all of the above recommendations produced by the Microbiological Standards Workshop.

Inorganic Chemicals

The Interim Regulations contain MCLs for the following inorganic chemicals:

Contaminant	MCL, mg/l
Arsenic	0.05.
Barium	1.
Cadmium	0.010.
Chromium	0.05.
Lead	0.05.
Mercury	0.002.
Nitrate (as N)	10.
Selenium	0.01.
Silver	0.05.
Fluoride	1.4 to 2.4, depending on climate.

Monitoring and reporting requirements were also included in the Interim Regulations for sodium and

corrosion. The above inorganic chemicals, and their associated monitoring requirements of one per year for surface water supplies and once per three years for ground water supplies, are being reviewed by EPA for possible inclusion, with or without modifications, in the NPDWR. Additional inorganic chemicals are also being considered as listed below. Inclusion in the list does not necessarily mean that regulations will be developed; other inorganics may also be included in the regulations if determined to be appropriate.

Aluminum	Sodium
Antimony	Nickel
Molybdenum	Zinc
Asbestos	Thallium
Sulfate	Beryllium
Copper	Cyanide
Vanadium	

The National Academy of Sciences has reviewed the existing regulations and has made recommendations regarding the adequacy of the regulations including suggestions on possible additions or deletions. The frequency and levels of occurrence of these inorganics in drinking water often vary regionally across the country; in some locations certain contaminants are found at levels of concern but in other locations, the contaminants have seldom been found. While many of the inorganics are natural contaminants of ground waters, some inorganics may occur in drinking water as a result of uncontrolled hazardous waste sites and thus, future contamination of water supplies may result if sources are not contained. Numerous inorganic compounds, such as lead, cadmium, and chromium, have been found, many times at relatively high levels, in leachates and runoff from hazardous waste sites. These pose a potential threat to surface water quality but primarily to ground water quality. Because of the slow movement and lack of self-cleansing characteristics of ground water, once contaminated, the ground waters will remain so for long periods of time. Other such sources include contamination of ground water with nitrate as a result of application of fertilizer on croplands.

Issues involving these contaminants include the frequency of occurrence, carcinogenicity, relative toxicity of different valence states, relative toxicity of inorganic vs. organic forms, adverse health effects vs. beneficial health effects or nutritional requirements, synergistic or antagonistic effects and the availability and cost of treatment. Comments are requested on each of these issues as they relate to each inorganic chemical as well as on specific issues raised in the discussions below of each compound. Commenters are also

requested to provide comments on the need for and levels for RMCLs and MCLs for each contaminant, the health risk of exposure, effective treatment methods and costs, and available monitoring techniques.

Inorganic Chemicals in the Interim Regulations

Arsenic. Although arsenic compounds may occasionally contaminate water sources as the result of industrial discharges or pesticide use, the occurrence of arsenic in drinking water is usually the result of ground waters being drawn from mineral formations containing natural arsenic ores. The areas affected include the southwest, northwest, northeast, and Alaska. Arsenic occurs in both trivalent and pentavalent states, as well as in organic forms. Trivalent compounds are more toxic than pentavalent compounds. The pentavalent state appears to predominate in foods, particularly seafood.

Arsenic has been considered by certain researchers to be an etiological factor in epidemic carcinoma of the skin and lungs and precancerous dermal keratoses. At this time, there is not an acceptable animal model demonstrating carcinogenic potential of arsenic. Recent findings indicate that arsenic may be a promoter of carcinogenesis rather than an initiator. Also, the carcinogenic risk may be a function of nutritional factors. No nutritional requirement for arsenic has been firmly established; however some authorities consider that trace amounts of arsenic are "nutritionally desirable".

Ion exchange treatment using anion exchange resins, activated alumina, bone char and reverse osmosis can remove both trivalent and pentavalent arsenic encountered in drinking water sources. Lime softening is effective for removing pentavalent arsenic but less effective for removing trivalent arsenic. Activated alumina absorption has been shown to be effective for arsenic removal from ground water sources.

Arsenic in drinking water has been included in the U.S. PHS standards since 1942. The current MCL for arsenic of 0.05 mg/l was derived from toxicity considerations other than carcinogenicity. The World Health Organization (WHO) guideline level for arsenic is also 0.05 mg/l.

At this time, it is not possible to speculate whether the existing MCL for arsenic should be altered from that in the Interim Regulations. Public comment is requested upon the basis for the RMCL: carcinogenicity vs. other effects, nutritional requirements vs. health risk;

and if RMCLs and MCLs should be set for separate valence states.

Barium. Barium is a natural mineral and deposits appear to be concentrated in the midwest. Virtually all cases on non-compliance with the Interim Regulations have resulted from barium in ground water sources.

Barium in drinking water was included in the U.S. PHS standards since 1948. The MCL for barium of 1 mg/l was based on projected effects on the peripheral nervous and cardiovascular systems. The derivation of the MCL was from inhalation data. An assumption was made regarding the absorption of barium into the blood stream from the gastrointestinal tract, which is reasonable for children but conservative for adults. The possible role of barium in drinking water in cardiovascular disease including hypertension is a matter of controversy and conjecture. Several aspects of barium toxicity are currently being investigated, including the gastrointestinal absorption rates and health effects following ingestion. Preliminary experimental findings have revealed that chronic, low-level barium ingestion produces increased blood pressure and EKG abnormalities in rats. The WHO has not established a recommended guideline level for barium.

Most treatment methods used for water softening are effective for barium removal. These methods include lime softening and ion exchange using either natural greensand or synthetic resins. Reverse osmosis is also extremely effective for barium removal.

Recent estimates of gastrointestinal absorption rates and the results of experimental and epidemiological studies indicate that the MCL for barium in the Interim Regulations needs to be revised. The NAS Safe Drinking Water Committee recommended that 4.7 mg/l provided an adequate margin of safety based upon adult intake and exposure parameters, but did not consider the higher uptake efficiency and water consumption rate of children. Public comment is requested on gastrointestinal absorption rates and cardiovascular effects of barium.

Cadmium. The presence of cadmium in drinking water is normally the result of corrosion of galvanized pipes and fittings. Also, cadmium may occasionally be present as the result of contamination of the water sources. There are very few instances where water systems have exceeded the current MCL for cadmium.

The MCL for cadmium was based on the intake necessary to produce proteinuria; while a significant source of intake could be cigarette smoking, this

was not taken into account.

Carcinogenic, mutagenic and teratogenic potential was not considered. Research is currently in progress to determine the effects of cadmium on the reproductive, nervous and cardiovascular systems. The critical concentration of cadmium in the renal cortex necessary for the development of proteinuria needs to be reinvestigated.

The most effective treatment methods for cadmium removal include lime and excess lime softening when cadmium is present as a contaminant in the water source. Cadmium levels resulting from corrosion can be reduced by implementation of an effective corrosion control program, including pH adjustment, calcium carbonate stabilization or addition of corrosion inhibitors.

Cadmium in drinking water has been included in the U.S. PHS standards since 1962. The current drinking water standard is 0.010 mg/l. The WHO guideline level for cadmium is 0.005 mg/l.

The derivation of an MCL for the NPDWR will entail consideration of many factors, including the additive or synergistic effects of cadmium and other trace metals in drinking water. Public comments are requested on: (1) the role of cadmium in reproductive, nervous, and cardiovascular dysfunctions; (2) the potential carcinogenic effects; (3) the importance of cadmium from other routes of exposure relative to drinking water and (4) monitoring requirements for corrosion-related cadmium in drinking water.

Chromium. The occurrence of excess chromium in drinking water is relatively infrequent and the result of contamination of water sources or use of chromates as corrosion inhibitors.

The MCL for total chromium (trivalent and hexavalent) was based on the toxicity of hexavalent chromium. Trivalent chromium is relatively non-toxic only very slightly soluble in water and is considered essential in man and animals for efficient lipid, glucose and protein metabolism. An MCL for chromium expressed only in terms of the hexavalent form is complicated by the likely conversion of trivalent to hexavalent chromium in drinking water sources under oxidizing conditions, such as during chlorination.

Hexavalent chromium exerts adverse effects on the renal, hepatic and gastrointestinal systems and the skin. Carcinogenic and mutagenic potential of this form of chromium has been shown.

Trivalent chromium can be effectively removed from drinking water by conventional coagulation techniques.

ailments has not been correlated with aluminum ingestion, but the apparent accumulation of aluminum in the brains and skeletons of dialysis patients has become a cause for concern.

Since aluminum in drinking water frequently results from water treatment with alum, the concentration of residual aluminum could be minimized by providing controls on the treatment process. Should severe restrictions be warranted, alternative coagulants could be required. Activated alumina, which also contributes some aluminum to drinking water, is used to remove a number of contaminants from drinking water. Cation exchange should be effective for removing aluminum from water, whether the aluminum is from natural sources or from water treatment.

In *Drinking Water and Health*, Vol. IV, the NAS calculated a 7-day Health Advisory of 5 mg/l but did not calculate any values for chronic exposure. The WHO guideline level for aluminum is 0.2 mg/l on the basis of aesthetic considerations. Consideration of any possible MCL would involve evaluation of relative exposure from drinking water versus other sources, health effect studies and control evaluations.

Antimony. There is no current MCL for antimony, but the development of an MCL has been suggested on the basis of possible health risks. Antimony resembles arsenic both chemically and biologically and symptoms of acute and chronic toxicity from antimony closely resemble those induced by arsenic.

The limited available occurrence data show that antimony has been found most often in tap water derived from surface sources, and while individual samples have been reported to contain as much as 90 mg/l, most reported positive samples contained less than 200 µg/l. The average concentration of positive samples of antimony in drinking water is probably in the order of a few µg/l. Mining operations and leaching from plumbing systems (tin/antimony solder) are possible sources of drinking water contamination, although there are only two antimony mining sites in the U.S. and tin/antimony solder is not widely used. The total antimony contribution from food and drinking water appears to be less than 100 µg per day on the average.

Three primary health effects are associated with exposure to antimony at high doses: pulmonary irritation and its consequences, dermatitis, and cardiovascular abnormalities. Toxicity symptoms also include gastrointestinal upset, irritability, sleeplessness, fatigue, dizziness and muscular pains. The pulmonary and dermal problems are mostly related to airborne antimony and

thus are generally found only in individuals working in the antimony industries. Most cardiovascular abnormalities (cardiac arrhythmias) have been attributed to the consumption of pharmaceutical preparations containing antimony. The latter are parasticides used to treat schistosomiasis, bilharziasis and leishmaniasis. However, patients with pre-existing cardiac and pulmonary conditions might find their ailments exacerbated by exposure to waterborne antimony and thus become a group at risk. Additional research is needed on the health effects of antimony derived from drinking water.

Antimony exists in natural waters with valences of three and five, as well as in two organic forms, methylstibnic and dimethylstibnic acids. Removal treatment for the inorganic forms includes ion exchange and reverse osmosis, while activated carbon should be effective for removal of the organic forms. Antimony(V) is by far the most abundant form in river waters.

EPA's "Ambient Water Quality Criteria for Antimony" contains a criterion of 145 µg/l for drinking water sources. The USSR has a limit of 50 µg/l for antimony. The WHO has not developed a guideline for antimony. The paucity of information on health effects attributable to the consumption of antimony from drinking water and the data on antimony occurrence in drinking water do not seem to warrant the establishment of primary drinking water regulations for antimony at this time.

Molybdenum. On the basis of occurrence of molybdenum in some surface waters, and on the basis of the association of molybdenum intake with the incidence of gout, the establishment of the MCL has been suggested.

Molybdenum is commonly found in ground and surface waters. However, unless the water originates from a processing or mining source, the molybdenum concentrations of positive samples are generally in the order of a few µg/l. Isolated cases of high molybdenum drinking water concentrations were reported in the proximity of open-pit uranium mines. Aqueous effluents from such sources as shale oil production and coal combustion may also introduce molybdenum to the aquatic environment.

Molybdenum is essential in the diet, as it is an integral part of five enzymes: aldehyde oxidase, sulfite oxidase, nitrogenase, nitrate reductase and xanthine oxidase. However, some investigators have reported increased blood and uric acid levels as the result of increased molybdenum intake.

Dietary molybdenum affects copper metabolism in many species. Data are available which suggest that copper depletion may result from molybdenum exposure of as low as 80 µg/l in drinking water. In India, molybdenum has been implicated in the formation of a recently identified bone-crippling disease, Genu valgum (knock-kneed syndrome). The NAS has estimated the average dietary molybdenum intake to be between 100 and 4600 µg/day. At the same time, the NAS cautions that molybdenum should not habitually exceed 500 µg/day. Persons consuming a diet at the high end of the range could possibly be at risk from molybdenum in drinking water.

Molybdenum is not removed to any great extent during conventional water treatment processes. Molybdenum as molybdate could be removed by anion exchange, and reverse osmosis should be effective for either the cationic or anionic forms of molybdenum.

The NAS recommends a dietary molybdenum intake of between 150 and 500 µg/day for adults. Some investigators recommend that drinking water molybdenum levels should not exceed 50 µg/l, but the need for an MCL is still under consideration. The WHO has not established a guideline level for molybdenum. In general it does not appear that the contribution of molybdenum from drinking water is significant, but high levels have been detected in drinking water in some areas.

Asbestos. This substance occurs frequently in drinking water both from natural mineral sources and from the degradation of asbestos-cement water pipe in contact with aggressive water. While airborne asbestos is a recognized health hazard, the effect of asbestos ingested from drinking water is unclear. The role of asbestos in the etiology of gastrointestinal cancer has been a matter of scientific controversy. Many aspects of asbestos have been the subject of intense investigation, including the health effects of ingested asbestos and the significance of asbestos exposure from asbestos-cement pipe. The WHO has not established a recommended action level for asbestos.

Asbestos in raw water sources can be removed by modified conventional coagulation and filtering techniques. Filtration alone is ineffective because of the small size of the asbestos fibers. When the source of asbestos is the deterioration of asbestos-cement pipes in contact with aggressive waters, calcium carbonate saturation of the water is effective. Other treatments showing promise for inhibiting

deterioration of asbestos-cement pipe include the use of zinc corrosion inhibitors, pH adjustment and lime stabilization.

Consideration of an MCL for asbestos fibers in drinking water involves factors ranging from analytical detection and counting methods to establishment of a dose-response relationship. The latter depends on the outcome of animal feeding studies, the most recent of which have not shown any adverse health effects from ingestion. An intensive seminar on this subject was conducted by EPA in October 1982. The results of the seminar will be published shortly. The epidemiology data on the occurrence of gastrointestinal tract cancer among occupationally exposed persons appears to be the most relevant issue relating to risks from ingestion from drinking water.

Sulfate. Sulfate is currently included in the secondary drinking water regulations because of its effect on the taste of drinking water. However, sulfate is a common water contaminant, and in some cases it occurs at concentrations high enough to cause laxative effects, particularly in those not acclimated to use of high-sulfate waters. Concentrations as high as 2,000 mg/l have been found in some public water systems.

Sulfate has been suspected as a contributing factor in the formation of various organ or duct calculi, but evidence establishing a relationship between the formation of these calculi

and sulfate concentrations in drinking water is lacking. Sulfate is extremely difficult to remove from drinking water. Anion exchange and reverse osmosis are reasonably effective. The WHO has a guideline level for sulfate at 400 mg/l based essentially on taste. The secondary MCL (SMCL) for sulfate is 250 mg/l.

Copper. Copper is currently regulated in the secondary drinking water regulations because of its effect on taste of drinking water. It is commonly found in drinking water from corrosion of copper pipes.

Copper is an essential nutrient, but there is no evidence of copper deficiency in the U.S. population except for isolated cases in patients maintained by total parenteral nutrition. Copper is toxic to monogastric animals when ingested in quantities that are 40 to 135 times greater than their respective requirements. Toxic effects from elevated drinking water levels have been reported especially for infants. Copper imparts an unpleasant taste to drinking water, which, along with an emetic effect, serves to limit the amount of copper which can be ingested from

drinking water. While the hazard to health from copper appears to be small for the general population, there are a few people who cannot tolerate even normal amounts of copper in the diet. These people are those suffering from Wilson's disease, an inherited autosomal recessive trait characterized by a disorder in copper metabolism which can lead to hepatic cirrhosis and to necrosis and sclerosis of the corpus striatum. A few people may also have a deficiency of glucose phosphate dehydrogenase which is believed to cause hypersensitivity to copper.

Since the occurrence of copper in drinking water is usually a result of corrosion, techniques for reducing the corrosivity of the drinking water are effective in limiting the presence of copper. The EPA SMCL and the WHO guideline action level for copper are 1.0 mg/l based on taste considerations, but development of primary drinking water regulations has been suggested based upon health considerations.

Vanadium. Vanadium occurs in both ground and surface water supplies, with the highest concentrations found near uranium-vanadium mining and milling operations or near industrial operations. The source of vanadium in the latter instances is fossil fuels which frequently have high vanadium contents. Although data are limited, the mean concentration of vanadium in tap water samples appears to be in the range of a few $\mu\text{g/l}$. Estimates of daily intake of vanadium from food and water average about 116 $\mu\text{g/day}$ with intake from drinking water from 4 to 7 percent of the intake from food. Air might contribute an additional maximum amount of 9 $\mu\text{g/day}$.

Chronic respiratory exposure to vanadium may decrease cholesterol synthesis, uncouple oxidative phosphorylation in liver mitochondria, and decrease urinary excretion of 5-hydroxyindoleacetic acid, with transient bilirubinemia and albuminuria. There is also some evidence that vanadium causes the appearance of scattered allergy-like eczematous skin lesions. However, there is no evidence of any chronic oral toxicity, probably because ingested vanadium is poorly absorbed. Vanadium may have nutritional significance, and it appears possible that the contribution of vanadium from drinking water to the daily intake may be beneficial.

The WHO has not established a recommended action level for vanadium. The beneficial aspects of vanadium intake and the absence of evidence of chronic oral toxicity do not appear to support the development of primary drinking water regulations for vanadium.

Sodium. Sodium is ubiquitous in drinking water and the levels detected vary from 0.2 to 260 mg/l or more in public systems and 0.2 to 622 mg/l in individual wells, according to the most recent survey. However, food is the major source of sodium intake in the vast majority of cases.

The available evidence indicates that excessive intake contributes to an age-related increase in hypertension in genetically susceptible individuals. The National Academy of Sciences has estimated that about 15 percent to 20 percent of the population are at the risk of developing hypertension. There is also a small segment of the population who are on severely restricted diets for various medical reasons and who must limit their total sodium intake. Development of an MCL has been suggested but since food is the major source of sodium intake and because of the difficulty and cost of removing sodium from water, the regulation of the sodium content of drinking water appears to be impractical. Some recent studies using drinking water sodium as a control variable have suggested slight blood pressure increases in some groups related to sodium concentration.

Sodium is probably the most difficult substance to remove from drinking water. Only the most rigorous treatment processes, such as distillation, reverse osmosis and deionization will remove sodium. It should be noted that virtually all other substances present in the water will be removed by these processes, and that reconstitution of the water following treatment will be necessary for the water to be acceptable on the basis of taste, corrosivity and desirable mineral content.

The current primary drinking water regulations contain a monitoring and reporting requirement for sodium. The dissemination of information on the sodium content of drinking water should enable those who must or wish to limit their sodium intake to adjust their diets according to their needs. The WHO recommended action level for sodium is 200 mg/l based on taste. Comment is requested on the evidence relating drinking water concentrations and elevation of blood pressure, and the significance of contribution of sodium from drinking water to the overall exposure and the need for the MCL.

Nickel. Nickel is seldom observed in fresh water. Natural nickel salts tend to hydrolyze to insoluble hydrolysates in water, so any nickel in surface or ground waters would likely be present in small amounts unless the presence of nickel was due to industrial pollution. The limited available data show that the

concentration of nickel in tap water usually does not exceed 20 µg/l and is likely to be present at average concentrations of a few µg/l or less. The average oral intake of nickel has been reported to be 300 to 600 µg/day. Inhalation exposure ranges from 2.4 µg/person/day, and the average intake from water is probably less than that from air.

Therefore, based on average food, water and air concentrations, most drinking water contributes a very small proportion of the daily nickel intake. Nickel salts, like the salts of copper and zinc, exert their toxic action mainly by gastrointestinal irritation and not by inherent toxicity. Nickel has long been thought to be relatively non-toxic, although nickel exposure has been associated with the development of occupationally related cancers of the lungs, larynx and nasal cavity. Contact dermatitis from exposure to nickel is well known. Quantities of nickel as minute as 58.7 µg/l have produced exzema in sensitized, susceptible individuals. Dietary nickel can aggravate nickel dermatitis. Apparently insoluble nickel compounds pass rather quickly through the gastrointestinal tract and have limited absorption.

Conventional water treatment processes (e.g., use of alum, lime or soda ash) do not appear to be effective for removal of nickel. Ion exchange and reverse osmosis would likely be effective.

The WHO has not established a recommended action level for nickel. The NAS does not view nickel in drinking water in terms of current levels as a cause for concern. In view of the usually low concentrations of nickel in drinking water and in view of the limited health effects aspects, the establishment of a limit for nickel in drinking water may not be warranted.

Zinc. Zinc is currently regulated in the secondary drinking water regulations based upon taste considerations. Zinc occurrence in drinking water is most frequently due to the corrosion of galvanized iron pipe and fittings. Some very high zinc concentrations have been noted when catchment systems made of galvanized iron were used to collect rain water for drinking purposes. Zinc is relatively non-toxic and is an essential trace element. A wide margin of safety exists between normal intake from the diet and the amount likely to cause oral toxicity. At drinking water concentrations high enough to cause gastrointestinal disturbances, zinc would impart a strong astringent taste and milky appearance to the water. Zinc interacts with other trace metals, and has a protective action against toxicity

of cadmium and lead. Some segments of the population of the United States may be marginally zinc-deficient.

Treatment for zinc reduction usually is limited to processes which reduce corrosivity of water, since the presence of zinc in drinking water is usually the result of corrosion.

The SMCL for zinc is 5.0 µg/l and the WHO recommends that zinc be kept below 5.0 µg/l for aesthetic reasons. Comment is requested on the need for an MCL for zinc.

Corrosion

The Interim Regulations include requirements to (1) determine the presence of specific materials in distribution systems and (2) to monitor for characteristics of corrosivity of the water. The water supplier must determine and report whether the following materials of construction are present in the distribution system:

1. Lead used in piping, caulking, interior lining of distribution mains, alloys and home plumbing.
2. Copper used in piping and alloys, service lines, and home plumbing.
3. Galvanized piping, service lines, and home plumbing.
4. Ferrous piping materials such as cast iron and steel.
5. Asbestos cement pipe.

The objective of obtaining this information regarding water quality and the presence of specific materials of construction was to enable the primary enforcement agency to determine which water supply system should initiate corrosion control measures.

Results of two independent studies estimate that approximately 16 percent of the public water systems in the United States distribute waters that are highly aggressive ($LI < -2.0$) (LI: Langelier Index), while an additional 52 percent distribute moderately aggressive waters ($-2.0 < LI < 0.0$). It is also known that only a limited number of these systems have instituted corrosion control measures.

Corrosion is a very significant concern not only affecting the aesthetic quality of the water but having a serious economic impact and posing health implication. Corrosion byproducts containing materials such as lead and cadmium have been associated with serious risks to the health of consumers of drinking water. In addition, byproducts of corrosion commonly include such compounds as zinc, iron and copper for which SMCLs have been set in the NSDWR; occurrence of these compounds, as a result of corrosion, should be considered indicators of possible deterioration of the distribution systems. Also, if corrosive waters are

leaching these compounds for piping materials, it is very likely that other compounds of health concern are also leaching from the pipes. Further, a number of epidemiological studies indicate that there may be an increased incidence of cardiovascular disease associated (however, this subject is still under investigation).

For many chemicals of concern, corrosion is the major source of drinking water exposure. For example, lead is seldom found in the water source but is commonly found in tap waters that are corrosive and are delivered through a distribution system using lead piping material or if lead is used as a constituent of solders used to join non-lead piping materials. Normal monitoring requirements, intended to determine the extent of contamination of the source water, are unlikely to characterize the exposure to high levels of lead that are associated with lead piping materials and solders that are expected to the distributed unequally throughout the distribution system.

Control of corrosion can be accomplished by a number of measures including pH adjustment, controlled alkalinity, addition of corrosion inhibitors or lime stabilization.

In setting the corrosion monitoring and reporting requirements in the Interim Regulations, consideration was given to setting an MCL for one or more of the various corrosivity indices, including the Aggressive Index (AI), the Ryznar Index (RI) and the Langelier Index (LI). The indices are not a direct measure of the corrosivity of the water but rather are indicators of the calcium carbonate stability which may be used to predict whether or not a calcium carbonate ($CaCO_3$) layer may be deposited and maintained on pipe surfaces to protect against corrosion. At that time these indices were determined not to be ideal as a determinant for corrosive characteristics of drinking water in all instances.

The approach being considered for the NPDWR is to set specific monitoring requirements for corrosion by-products, such as lead and cadmium, that would address the problems of obtaining representative samples to assess water quality. The definition of "compliance" with an MCL will be revised to assure that averaging will not permit portions of a water supply to exceed an MCL on a continuing basis. Specifically, systems that have known corrosive water or which have piping materials that are susceptible to corrosion will be required to take sufficient samples in their distribution systems so that the State can be assured that the MCLs for

the corrosion by-products will not be exceeded in various parts of the distribution system. Comments are requested on this approach and on what specific monitoring requirements should be set. Also, any available new information on the use of corrosion indices is requested.

Synthetic Organic Chemicals (SOCs)

The Interim Regulations contain MCLs for the following organic chemicals:

Contaminant	Interim regulations MCL, mg/l	WHO Recommended Limit
Endrin	0.002	
Lindane	0.004	0.003
Methoxychlor	0.1	0.030
Toxaphene	0.005	
2,4-D	0.1	0.1
2,4,5-TP (Silyl)	0.01	
Total Trihalomethanes	0.10	0.030

* For chloroform only.

These organic chemical MCLs, with the exception of trihalomethanes and their associated monitoring requirements, are being reviewed at this time for possible inclusion in the NPDWR. The total trihalomethane (TTHM) regulations have only recently taken effect, and then only for a limited segment of public water systems; it would be premature to consider revisions at this time. The entire area of disinfection by-products and alternative disinfectants will be considered at a later date. Experience must be gained with the full implementation of the regulations. Also, further health effects data are required in order to evaluate the potential health risks to these substances.

In the U.S., establishment of limits for pesticides in drinking water began with the advisory groups engaged in revising the 1962 Public Health Service drinking water standards. Virtually no cases of non-compliance with the current MCLs have been reported. The USSR's drinking water standards (1970) listed a number of these pesticides among the approximately 200 organic chemicals for which limits were set.

A number of other synthetic organic chemicals are being considered for inclusion in the NPDWR including a number of registered pesticides. These include:

Aldicarb
Chlordane
Dakapon
Diquat
Endosulfan
Glyphosate
Carbofuran
1,1,2-Trichloroethane
Vinclozolin
Simazine
PAHs
PCBs

Atrazine
Phthalates
Acrylamide
Dibromochloropropane (DBCP)
1,2-Dichloropropane
Pentachlorophenol
Picloram
Dinoseb
Alachlor
Ethylene dibromide
Epichlorohydrin
Dibromomethane
Toluene
Xylene
Adipates
Hexachlorocyclopentadiene
2,3,7,8-TCDD (Dioxin)

Inclusion of specific SOCs on the above list was based upon the occurrence of the SOC in drinking water and the potential health effects of exposure to that SOC. The pesticides included in the above list have either been detected in drinking water, are registered for use in or around drinking water, or are used in such a manner that the potential exists for entering drinking water supplies. Inclusion in the above list does not necessarily mean that regulations will be developed for the SOC but that these are SOCs currently being considered; other SOCs not listed may also be considered and included in the NPDWR. Determination of which SOCs should be included in the NPDWR will be based upon an analysis of the significance of potential human exposure, associated health effects of exposure, and other pertinent factors. Brief discussions of the pesticides included in the Interim Regulations are provided below and are followed by a discussion of several of the other SOCs under consideration.

Organic Chemicals in the Interim Regulations

Chlorinated Hydrocarbon Insecticides. The Interim Regulations contain MCLs for endrin, lindane, methoxychlor and toxaphene. The NAS, in *Drinking Water and Health* (1977), considered lindane to be an animal carcinogen and endrin to be a suspected animal carcinogen. The NAS derived a risk estimate for lindane of 5.6 to 13×10^{-6} per microgram per liter for lifetime exposure. This corresponds to a concentration level of 77 to 180 nanograms per liter (ng/l) at the 10^{-6} risk rate.

The EPA Carcinogen Assessment Group derived excess cancer risk estimates for exposure to lindane in ambient water (U.S. EPA, 1980). Assuming the ingestion of two liters of drinking water/day and 6.5 grams/day of contaminated fish and seafood, a water concentration of 18.6 ng/l was estimated to yield a one in one million

risk over a lifetime. The Carcinogen Assessment Group recently recalculated their excess cancer risk estimates for lindane. Assuming consumption of 2 liters of water per day, a concentration level of 32 ng/l was estimated to result in a one in a million risk over a lifetime.

The NAS felt that there were insufficient data on which to base an estimate of cancer risk for endrin. For methoxychlor and toxaphene, the NAS derived ADIs of 0.1 mg/kg/day and 0.00125 mg/kg/day, respectively.

It is important to note that NAS established the ADI for toxaphene before the NCI bioassays in rats and mice were completed. Under the conditions of testing, toxaphene was found to be carcinogenic in mice of both sexes (increased incidence of hepatocellular carcinoma). The test results also suggested carcinogenicity of toxaphene for the thyroid of rats of both sexes.

Chlorophenoxy Herbicides. The NAS also derived ADIs for the two chlorophenoxy herbicides, 2,4-D and 2,4,5-TP. These were 0.0125 and 0.00075 mg/kg/day, respectively. The food additive tolerance level established for 2,4-D in water is 0.1 mg/l, identical to the MCL for this substance in the Interim Regulations.

Other Synthetic Organic Chemicals (SOCs) Under Consideration

Other Pesticides. A number of other pesticides are registered by EPA for uses which may result in their presence in drinking water sources. During the registration process under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and acceptable residue limit in drinking water is determined for each of the aquatic use pesticides, but not for other pesticides. Depending upon the quality of the available data, these allowable limits may be of a permanent or temporary nature. Allowable limits for certain of the aquatic use pesticides are listed below:

Compound	FIFRA derived acceptable pesticide limit	ADI (per NAS)
Dakapon	0.2 ppm	
Diquat	0.1 ppm	
Endosulfan	0.2 ppm*	
Glyphosate	0.1 ppm	
Simazine	0.5 ppm	0.215 mg/g/day.

* Temporary limit.

Other pesticides which have been reported to occur, at least occasionally, in drinking water sources include chlordane, aldicarb, carbofuran, pentachlorophenol, dibromochloropropane (DBCP), dinoseb,

- The analytical methods for detecting and quantifying radionuclides.
- Monitoring requirements for radionuclides.

- The treatment for removing radionuclides from drinking water, its cost and general availability.

- Waste management practices for removal of radionuclides from drinking water.

- Methodology for protecting against multiple exposure.

VI. References

The following references are available from the addresses listed at the beginning of this notice.

Assessment of Microbiology and Turbidity Standards for Drinking Water, EPA, ODW, 1983.

National Interim Primary Drinking Water Regulations, Amendment Trihalomethanes, 48 FR 8406, February 28, 1983.

Fluoride: Response to Petition from South Carolina, 46 FR 58345, December 1, 1981.

Ronald Reagan, Executive Order 12291, 46 FR 13193, Feb. 19, 1981.

Safe Drinking Water Act Reauthorization, 47 FR 670, January 6, 1982.

"Small Systems Strategy", 45 FR 40222, June 13, 1980.

The following documents are available from the sources indicated:

National Interim Primary Drinking Water Regulations, NTIS, Accession No. PB 257530.

Drinking Water and Health, Vols. I, II, III, IV, V. National Academy of Sciences, Washington, D.C.

Manual of Treatment Techniques for Meeting the Interim Primary Drinking Water Regulations, EPA ORD, MERL, Water Supply Research Division, Cincinnati, Ohio 45260.

Evaluation of the Microbiology Standards for Drinking Water, NTIS, Accession No. PB 297119.

VII. Request for Public Comments

Public comments and information on all aspects of the issues presented in this ANPRM are requested to assist EPA in determining the appropriate regulatory approaches and specific requirements of the NPDWR. Supporting information is requested for any comments provided. For microbiological, inorganic, organic, and radionuclide contaminants, the following questions are being examined.

- What criteria should be used to determine which contaminants should be in each category? What contaminants should be included in Category I, Category II, and Category III as described?

- Is waiving certain MCLs when susceptible populations are not affected an appropriate approach? For which contaminants? Could this be used as one criteria for determining which Category would be appropriate for certain contaminants?

- What level should be established for each RMCL?

- What safety factors should be used in conjunction with chronic toxicity data in RMCLs for non-carcinogens?

- Is using the ADI an appropriate method for establishing RMCLs for non-carcinogens?

- By what method should RMCLs be set for carcinogens?

- What level should be established for each MCL?

- What criteria should be used to identify Generally Available Technology (GAT) under the SDWA? Engineering and technical feasibility factors? What factors affect "reasonable" cost determinations? What is a reasonable cost for the consumer?

- How should system size, water quality and other factors be incorporated in the GAT? Should "non-conventional" solutions such as bottled water and point-of-use treatment devices be considered acceptable means for achieving compliance?

- What requirements should be set for monitoring for each type of contaminant?

- What frequency of monitoring would provide adequate measurement of water quality within the feasible means of water systems?

- Which analytical methods are most reliable and what are the costs involved?

- What limits of measurement accuracy and precision should be set for each analytical method?

- What reporting requirements should be established to provide an efficient means of determining compliance while minimizing paper work burdens on public water systems and State programs?

A public meeting and four public workshops will be held for the interested public to comment and provide information and data on the regulatory approaches and other issues presented here. Dates and locations of the meeting and workshops are provided in the Dates section of this notice.

List of Subjects in 40 CFR Part 141

Chemicals, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: September 27, 1983.

William Ruckelshaus,

Administrator.

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