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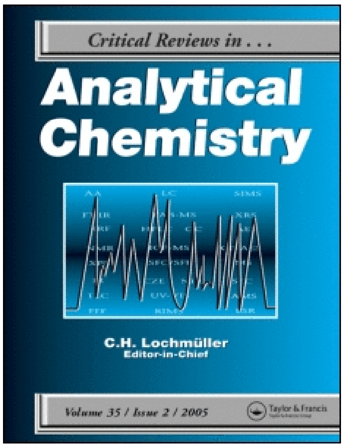

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EPA Analytical Methods for the Determination of Pollutants in the Environment

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ABSTRACT: The mission of the United States Environmental Protection Agency (EPA) is to protect human health and safeguard the natural environment. EPA was established to implement and enforce environmental regulations passed by the U.S. Congress to control pollutants discharged into the air, water, and land. To implement these regulations, EPA develops test procedures (analytical methods) to measure regulated pollutants. These methods are contained in regulations codified at Title 40 of the U.S. *Code of Federal Regulations* (40 CFR). Nearly all of the current test procedures are prescriptive, meaning that they contain exacting procedures for performing tests. Recently, EPA has initiated an effort to implement a performance-based measurement system (PBMS) that will introduce flexibility in conducting environmental monitoring. This initiative will encourage analytical innovation by allowing the use of new and alternate methods provided that predetermined performance criteria are met. This article presents an overview of EPA's analytical methods programs and implementation of PBMS and provides detailed information on EPA's wastewater monitoring program.

KEY WORDS: natural environment, regulated pollutants, performance-based measurement system.

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I. U.S. ENVIRONMENTAL LAWS

Since the mid-1950s, major sources of pollution in the U.S. have been linked to both industrial and municipal wastes. These wastes, including discharges to air, water, and land, have been found to contain pollutants that cause adverse impacts on living organisms. Growing environmental concerns about these harmful effects led the U.S. Congress to pass environmental legislation mandating that EPA control emission and discharge of pollutants into air, water, and land, and regulate use and distribution of toxic substances. These laws are implemented by EPA in the form of regulations published at 40 CFR.

II. REGULATED POLLUTANTS

Lists of regulated pollutants are frequently developed to facilitate EPA in implementing laws passed by the U.S. Congress. Examples of these regulatory lists include:

- Priority Pollutant List — Wastewater Program
- Drinking Water Priority List (DWPL) — Drinking Water Program
- Hazardous Substances List (HSL) — Solid Waste Program
- Superfund Target Compound List (TCL) — Remedial Response Program
- Emergency Planning and Community Right to Know Act List (EPCRA) — Emergency Response Program
- Groundwater Monitoring List (GML) — Solid Waste Program
- National Emission Standards for Hazardous Air Pollutants (NESHAPS) List — Air Monitoring Programs

More than 25 lists of substances are regulated under the various EPA programs. The number of substances on these lists range from as few as 5 to as many as 750. These lists do not include the more than 5000 substances reported to EPA's Office of Prevention, Pesticides, and Toxic Substances.

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III. POLLUTANTS REGULATED IN EPA'S WASTEWATER PROGRAM

EPA's Office of Water develops regulations to control the discharge of pollutants to surface waters of the U.S. A major component of developing regulations for control of the discharge of pollutants is the selection of individual pollutants for regulation. To select pollutants for inclusion in regulatory lists, EPA reviews technical literature, collects industry data, and conducts detailed sampling and chemical analysis of raw and treated wastewater at several representative sites in an industrial category or subcategory. These studies determine which pollutant is present and at what concentrations, the performance of pollution control technologies, and the location at which effective removal can be implemented (for example, in-plant or end-of-pipe). Additionally, EPA implements different pollution control systems for the removal of different classes of pollutants, for example, metals *vs.* organics. Depending on which matrix is being monitored, limitations established for a particular pollutant may vary among the industrial categories and subcategories.

Discharge limits, standards, and guidelines have been established for three classes of pollutants: conventional pollutants, toxic pollutants, and nonconventional pollutants.

A. Conventional Pollutants

Clean Water Act Section 304(a)(4) identifies five conventional pollutants. This group consists of the following five "parameters". These parameters are generic in character, in that they are not specific compounds but are classes of substances that have similar physical, chemical, or biological responses to empirical laboratory tests.

- Biochemical oxygen demand (BOD)
- Total suspended solids (TSS)
- Fecal coliform
- pH
- Oil and grease

B. Toxic Pollutants

As part of the Clean Water Act (CWA) amendments of 1977, Congress identified 65 pollutants as toxic [CWA Section 307(a)]. This priority pollutant list was expanded to 129 and later reduced to 126 pollutants. Regulations are required for toxic pollutants that are:

- Present in greater than trace concentrations
- A significant hazard to human or environmental health
- Above treatability levels in raw waste streams
- Pass through or interfere with the operation of Publicly owned treatment works (POTWs)

Specific parameters include, but are not limited to, 13 metals, 25 pesticides/PCBs, 2378-TCDD, cyanide, and asbestos.

C. Nonconventional Pollutants

In addition to the Conventional and Toxic pollutants, EPA is required to identify and regulate other pollutants. Generically, a "non-conventional pollutant" is any pollutant or pollutant parameter that is not identified as either conventional or toxic. Examples include:

- Toxicity (acute or chronic)
- Chemical oxygen demand (COD)
- Metals and organic compounds not on the priority pollutant list
- Radioactivity
- Color

IV. ANALYTICAL METHODS FOR WATER

Under Section 304(h) of the Clean Water Act (CWA) and Sections 1445(a) and 1450(a) of the Safe Drinking Water Act (SDWA), EPA is required to publish test procedures to measure environmental pollutants. These methods are promulgated at Title 40 of the U.S. *Code of Federal Regulations* (CFR) part 136 for wastewater and part 141 for drinking water.

Prior to publication in the CFR, the method and supporting technical and regulatory information are proposed in the *Federal Register*, the official publication of the U.S. Government. A comprehensive summary of the regulatory background and the technical rationale for the methods is given in the preamble to the regulation. In

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the proposal phase, comments on the regulation are solicited from the public. Proposal of a method ensures that the regulation development process is conducted in a free and open environment. The process enables all members of the public, including concerned environmental groups and the regulated industry, to have the opportunity to comment on the regulation before it is enacted. After a comment period, usually 60 days, EPA evaluates the comments and data received to determine whether the method should be promulgated, changed, or withdrawn. If the comments and data are compelling, the method is changed or withdrawn; otherwise, the method, along with any negotiated changes, is published as final in the *Federal Register* and included in the next revision of the CFR. After promulgation, and if an interested or affected party still believes that the method is deficient or is not fair for some reason, that party has the opportunity to bring legal action against EPA.

A. Method Categories

Methods promulgated for monitoring discharges can be classified into five general categories based on what is measured:

1. Conventional/classical
2. Metals
3. Organics
4. Toxicity
5. Microorganisms

Methods for the conventional/classical analytes normally use simple determinative techniques such as:

- Colorimetry
- Spectrophotometry
- Weighing
- pH measurement

Methods for metals use determinative techniques such as:

- Flame and furnace atomic absorption spectrometry
- Inductively coupled plasma (ICP) spectrometry
- ICP/mass spectrometry (MS)
- Ion chromatography
- Colorimetry

Methods for organics use determinative techniques such as:

- Gas chromatography (GC) with a variety of detectors
- GC followed by low- and high-resolution MS
- High-performance liquid chromatography

Toxicity methods include techniques for whole effluent toxicity using a variety of organisms. Methods for microorganisms include fecal and total coliform.

Special apparatus and techniques are employed as required for unique and unusual circumstances. For example, in the determination of chlorophenolics to establish regulations for the Pulp, Paper, and Paperboard industry, *in situ* derivatization combined with isotope dilution low-resolution MS was used to reliably identify and quantify the analytes of interest.

B. Quality Control (QC)

The majority of newly developed EPA methods have standardized QC criteria. This QC consists of a "start-up" test, instrument and calibration checks, analysis of blanks, and spikes of the analytes of interest into wastewater samples to determine accuracy.

The start-up test is performed when the method is first practiced and any time that it is modified. The test consists of an analysis of four replicates of the analytes of interest spiked into reagent water. QC limits for the results of the test are provided in a table at the end of each method. The purpose of this test is twofold: it requires the laboratory to demonstrate proficiency prior to using the method, and it provides a means for permitting method flexibility (described below).

The analysis of blanks ensures that the analytical system is free from contamination and

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interferences, and can be used to detect carry-over of the analytes from one sample to another.

The analysis of spikes into wastewater samples permits laboratory and matrix effects to be separated. A table at the end of each method gives the expected recovery for each analyte. If the recovery is not within the range specified, a check is made on the analytical system by analysis of a QC check standard. If the recovery of the QC check standard is within the normal range, the analytical system is working properly and a matrix effect is present. In this case, the result cannot be reported for regulatory compliance purposes. If the recovery of the QC check standard is not within the normal range, the analytical system is not performing properly and must be repaired, and the analysis of the sample repeated.

V. EPA'S ENVIRONMENTAL MONITORING METHODS INDEX

In 1986, EPA developed a database specifically designed to track the proliferation of regulatory lists with their associated substances and methods for analysis. This database, the Environmental Monitoring Methods Index (EMMI), was selected as EPA's official methods compendium by the Agency's Environmental Monitoring Management Council in the early 1990s. The Engineering and Analysis Division within EPA's Office of Water is responsible for maintaining and updating the EMMI database.

The substances listed in EMMI are termed "analytes", reflecting that the primary focus of EMMI is information related to the measurement of the analyte. Information about each analyte in EMMI includes the common name, the Chemical Abstracts Service (CAS) Registry Number and CAS Name (if available), the IUPAC name (where appropriate), common synonyms, the regulatory list(s) on which the analyte appears, the regulatory limit for the analyte on each list (if applicable), and the chemical and use categories for the analyte. List names were chosen to be most familiar to EPA personnel and others familiar with EPA regulations. A separate list description supports each list. Also included is a reference to the part of the EPA organization responsible for the list, and the reference document from which the list is taken. The EMMI database provides a concise means by which a large and diverse number of lists can be tracked.

A. Methods in EMMI

EMMI contains abstracts of 3500 analytical methods. The majority of these are EPA methods. The methods in EMMI include wastewater methods, drinking water methods, air methods, solid waste methods, pesticide methods, toxic substance methods, emergency response (Superfund) methods, and others. This diversity of methods is the result of each program office developing methods to meet its particular analytical needs in response to a new law or a court order to have a regulation in place by a particular date. Method abstracts contain a detailed summary of the preparative and determinative steps used to detect, identify, and quantify the analyte(s) of interest. For the analytical chemist, the abstract is usually sufficient to demonstrate that a given technology can be used for analysis of an environmental sample containing the analyte.

In addition to methods developed by EPA for measurement of environmental pollutants, methods have been developed by the American Public Health Service (APHA), the Association of Official Analytical Chemists (AOAC), the U.S. Geological Survey (USGS), The American Society for Testing and Materials (ASTM), the U.S. Department of Agriculture (USDA), branches of the military, and others. When added to EPA methods, the list of methods becomes formidable. A second objective of EMMI was to track EPA and non-EPA environmental analytical methods for analytes on the regulatory lists.

VI. APPLICATION OF METHODS TO DETERMINING EFFLUENT LIMITS IN EPA'S WASTEWATER PROGRAM

Since 1977, EPA's Engineering and Analysis Division (EAD) has been applying methods to analysis of wastewater and has been promulgating effluent limitations and guidelines based on

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results of analyses of industrial effluents using these methods. From 1977 to 1980, EAD used mainly GCMS "screening protocols" for analysis of the organic pollutants. In 1980, EAD began to use isotope dilution Methods 1624 and 1625 nearly exclusively for data gathering. The use of Methods 1624 and 1625 was in response to criticisms from the industries being regulated that the data received by EPA contained false positives and was not of the highest precision and accuracy. Use of the isotope dilution methods has reduced these criticisms considerably.

In controlling pollutants discharged into wastewater, EAD studies the characteristics of the treatment systems that can be applied to removal of a particular pollutant or pollutant group. For example, a high concentration of vinyl chloride in wastewater can be removed by steam stripping. By measuring the concentration of vinyl chloride in the water at the inlet to a given steam stripper and at the outlet from the steam stripper, the stripping efficiency can be measured. By measuring the inlet and outlet concentrations at many steam strippers, the steam strippers that perform best can be determined. Finally, by comparing steam strippers with other technologies that can remove vinyl chloride from wastewater, the best technology for vinyl chloride removal is known. The resulting regulation will then specify the residual level of the pollutant, based on the best technology (one regulation specifies the removal efficiency for use at the best practicable technology level of control).

A. Use of Methods for National Pollutant Discharge Elimination System (NPDES) Permits

The regulations that control discharge of pollutants into wastewater require the use of methods promulgated under section 304(h) of the Clean Water Act for monitoring in NPDES permits. For conventional pollutants, the toxic organic pollutants, the toxic metals pollutants, and for the nonconventional pollutants, these are methods promulgated or incorporated by reference at 40 CFR Part 136. For some regulated industries, different or additional methods may be promulgated as a part of the regulation for that industry.

B. Method Flexibility

When a major set of methods was first proposed by EPA in 1979 (44 FR 69464), two distinctly different types of comments were received. One comment was that the methods should include rigorous procedures and QC limits with no flexibility; the other was that nearly unlimited flexibility should be permitted. In response to these comments and to allow for improvements in analytical technologies, EPA decided that certain "minor" modifications would be considered within the scope of these methods, provided that the start-up test was repeated each time a modification was made and that the results of the start-up test met the QC limits in the table provided at the end of each method. Examples of minor modifications are the use of alternate GC columns (including capillary columns) and alternate concentration techniques in the organic methods, and use of alternate digestion procedures in the metals methods.

VII. EPA'S PERFORMANCE-BASED MEASUREMENT SYSTEM INITIATIVE

As part of an Agency-wide effort to improve environmental data gathering, EPA is considering implementing a performance-based measurement system (PBMS) approach to environmental measurements. PBMS emphasizes method and laboratory performance rather than prescriptive procedures. Under PBMS, data producers would be required to document method performance and certify the appropriate use of quality assurance and quality control (QC) procedures. The system would apply to physical, chemical, and biological methods used in laboratories and methods used in the field. The goals of PBMS are to provide flexibility in conducting required environmental monitoring, encourage early introduction of innovative technologies, involve stakeholders in method development, and encourage more cost-effective monitoring

PBMS is defined by EPA as "a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective

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manner". Under PBMS, EPA would specify performance criteria, and it would be incumbent on data producers to prove that results produced achieved the performance criteria.

A. Implementing PBMS

EPA's early efforts focused on defining the performance criteria necessary to assure that measurements met EPA's monitoring needs. However, these early efforts did not fully address implementation. It was clear that key issues associated with implementation were not the same from program to program, and perceived hurdles varied widely. As a result, EPA has decided that PBMS will be implemented in each program according to the needs of that program. For example, EPA's Office of Solid Waste and Emergency Response plans to implement PBMS by allowing any method so long as the DQOs/MQOs for the program or project are met, whereas EPA's Office of Air and Radiation and EPA's Office of Water plan to implement PBMS through use of performance criteria associated with a reference method. Any modification or new method could be used so long as the performance criteria are met.

To assist the programs in developing PBMS, EPA has adopted the following six goals:

1. Provide a simple, straightforward way for the regulatory community to respond to specific measurement needs with reliable, cost-effective methods.
2. Emphasize project- or application-specific method performance needs rather than requiring that specific measurement technologies be used in order to reduce the cost of measurements.
3. Encourage the use, by the laboratory community, of professional judgement in modifying or developing alternatives to established Agency methods.
4. Employ a consistent way to express method performance criteria that is independent of the type of method or technology. This includes articulating measurement needs in qualitative and quantitative terms.
5. Foster new technology development and continuous improvement in measurement methodology, by providing qualitative and quantitative targets for identified measurement gaps to method developers and other researchers.
6. Encourage the measurement community to give the agency feedback on new monitoring approach successes as well as failures in order to expand our knowledge of new or modified approaches and to assist others by helping to disseminate this information to the wider monitoring community.

Under PBMS, laboratory inspections should change little. Inspectors would continue to review data, interview personnel, inspect equipment availability and operation, and verify that documentation and data support method performance claims. As EPA programs have evolved, even the most experienced laboratory inspectors have found it challenging to be familiar with all analytical procedures and analytes. PBMS would de-emphasize the importance of complying with specific analytical procedures and emphasize documentation, QC, and data review. PBMS would might improve EPA inspections by ensuring a detailed review of analytical records and documents and could improve data quality by providing greater assurance that a method is meeting data quality needs.

To comply with PBMS, data producers would have to certify method performance and to make available such supporting documents as a written copy of the method (containing all critical elements of EPA's method format) and all appropriate standard operating procedures. As currently envisioned, the system would rely heavily on self-certification by the laboratory and periodic verification by EPA. A copy of the certification form would be retained on-site for subsequent inspection by the regulatory authority, if desired.

VIII. OFFICE OF WATER PBMS IMPLEMENTATION

In developing its PBMS program for water measurements, EPA's Office of Water has identified three potential approaches to implementing PBMS:

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1. *Performance criteria only*: This approach provides nearly unlimited flexibility. It makes new methods and modifications legally equivalent to existing methods and requires no EPA preapproval or prenotification of regulatory authorities. One comment received by OW on the approach to using performance criteria only noted that it would increase difficulty of enforcement and require that States have an increased knowledge and awareness of the development of new methods and method modifications.
2. *Reference method/performance criteria:* This approach provides controlled flexibility. By combining a reference method with performance criteria, new methods and modifications would be legally equivalent to existing methods, but would require prenotification of regulatory authorities for new methods only. The reference methods specify well-defined documentation and validation requirements and maintain ease of enforcement. Comments from the States indicated that it would be less burdensome than option 1 to implement.
3. *Performance-based compliance*: This approach applies only to compliance monitoring. It shifts the focus to compliance evaluation and does not necessarily require methods, but requires that a laboratory know every compliance limit for every analyte in a permit. It also requires that the regulatory authority know about all means of achieving compliance

Based on comments received from the regulated community, states, and the analytical community, OW decided to implement a reference method/performance criteria approach. To implement PBMS, regulators or project managers would define the performance criteria for a measurement based on an established reference method or a data quality objectives (DQO). EPA would continue to identify, develop, and maintain reference methods that meet specific program needs to ensure that performance expectations and criteria remain realistic and properly reflect the state of science.

EPA's Office of Water has developed a draft implementation plan for PBMS in EPA's water programs, and published a proposed rule to implement PBMS in March 1997 (62 FR 14976, March 28, 1997). The OW implementation uses a tiered approach to validation of a new method or method modification. In this tiered approach, the level of validation is consistent with the intended use. For use in a single laboratory, validation consists of an initial demonstration of method performance and ongoing tests to ensure that performance remains within the performance criteria of a reference method. For nationwide use, validation consists of an initial demonstration and tests of a minimum of nine matrix types in a minimum of nine laboratories (each laboratory tests one matrix type only).

A. Data Quality Objectives (DQOs), Measurement Quality Objectives (MQOs), and Performance Criteria

EPA currently uses a seven-step data quality objective (DQO) process to convert data needs into an optimized study design that balances those needs against resources. Trade offs are often made between data confidence and cost. If both field error and measurement error are known, decision makers can determine the level of false positive and false negative errors they are willing to tolerate. With these pieces of information they can then develop an optimal sampling and analysis design using the DQO process. To achieve DQOs for a study, while controlling costs, project managers must have the flexibility to select among methods.

Analytical method performance can be measured in terms of critical data quality elements, such as bias, precision, sensitivity, selectivity, detection limit, and range. EPA reference methods contain performance criteria for these elements. In the DQO process these elements are specified as measurement quality objectives (MQOs), and EPA project managers would normally specify these MQOs as a part of the DQO development process. A difficulty in the DQO/MQO process in knowing what performance is practical. If an excessively stringent MQO is specified, the laboratory will be unable to achieve the performance. As a solution to this problem, project managers can look up the performance criteria in

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a reference method and specify the performance as the MQO.

B. Monitoring under PBMS

EPA is aware that advanced monitoring technologies have great potential to improve the agency's ability to monitor new contaminants not amenable to existing methods. Recognizing the problems and potential benefits, the agency is considering PBMS to allow the regulated community to use new or emerging technologies to meet mandated monitoring requirements. Under PBMS, the emphasis would shift from how to gather data to how to document its quality. The current system provides a reassuring security of rigid rules, but it does not necessarily provide the data quality needed to make decisions that protect the environment. In the proposed PBMS, personnel performing measurements would be responsible for demonstrating method performance, and their organizations would be responsible for certifying performance and for maintaining the prescribed data records that support their conclusions.

In those compliance monitoring programs that allow some limited analytical flexibility (e.g., for organic wastewater protocols), EPA has had few safeguards in place. The prescribed methods sometimes allow different preparation steps (extractions, cleanup) and instrumentation procedures (chromatography conditions and detectors). PBMS offers near unlimited analytical flexibility, but incorporates critical criteria to assure analytical performance.

Currently, most methods prescribe a series of steps designed to produce desired results under typical conditions. Incorporated into many of these methods are QC procedures designed to help analysts verify that the system or instrument is "in control" during operation and to allow data users to evaluate results. While the value of such rigid specifications is debatable, they are, nonetheless, a component of the current compliance monitoring system. PBMS provides measurement flexibility, giving data producers and regulators the opportunity to select the most cost-effective method that meets EPA's measurement needs. In addition, PBMS should encourage innovations in measurement technologies. PBMS should especially facilitate the use or approval of moderate changes to agency-approved reference methods and result in continuous improvement to the agency's measurement capabilities.

IX. STREAMLINING APPROVAL OF ALTERNATE TEST PROCEDURES

In compliance monitoring programs that allow alternative test procedures (ATPs) or methods, users must obtain written permission from a state and concurrence from the EPA Regional Administrator (for wastewater methods) or a designee of the EPA Administrator (for drinking water and air methods). Regulators base approval on whether an alternative procedure or method is substantially equivalent to a prescribed method. Letters of approval for use at a particular facility usually take no more than a few months. However, an ATP to be proposed and promulgated through the regulatory process for inclusion in the *Code of Federal Regulations* can take years. As a result, users have submitted few requests. Those submitted often come from manufacturers of analytical instruments whose vested interest in the alternative technique provides incentive to endure the arduous approval process.

As part of its goal to increase method flexibility, the Office of Water has streamlined procedures for validation and approval of Alternate Test Procedures and new methods. These procedures have been revised to significantly reduce the number of analyses necessary to demonstrate method equivalency (i.e., equivalency to an EPA-approved method) by removing the requirement for side-by-side analyses using two different methods. Instead, applicants are required to demonstrate method equivalency by meeting quality control (QC) acceptance criteria associated with EPA-designated approved methods for different combinations of regulated analyte and determinative technique. In 1998, OW published revised protocols for approval of new methods and ATPs for chem-

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istry and whole effluent toxicity. OW is currently developing a streamlined protocol for approval of microbiological methods.

X. FUTURE NEEDS AND DEVELOPMENTS

A. Control of Nonconventional Pollutants

The current environmental statutes give EPA the responsibility to set effluent limits for any analyte (see the examples of nonconventional pollutants above). As a result, the agency is continually adding analytes to the target lists in an effort to reduce water pollution to levels consistent with its mandate. At present, EAD tests for 416 specific analytes in selected wastewaters. This list is exclusive of the total list of 209 polychlorinated biphenyl (PCB) and 135 chlorinated dioxin and furan isomers and cogeners that EAD also tests for. As other pollutants are found to be of environmental concern, they are added to this list. These additions are usually the result of new environmental legislation.

B. Water Quality-Based Limits

In developing technology-based regulations for control of pollutants in wastewater, EPA has recognized that the reduction or elimination of the conventional and toxic pollutants that the agency can measure and regulate may not improve the quality of the receiving water. Therefore, EPA is studying the effects of the technology-based regulations on human health and aquatic life. However, because the regulations often take years to implement and the treatment systems take time to install and optimize, EPA may not learn of these effects for many years. As a result, the agency is developing analytical methods that directly address the issue of water quality.

One of the major efforts is in measurement of chronic and acute toxicity, using a variety of test organisms. As with the development of methods for determination of the toxic organic pollutants and toxic metals pollutants, methods for determining toxicity will not mature instantaneously. However, EPA will apply these methods as they mature to control pollutants in wastewater and thereby meet the agency's mandate to protect human health and aquatic life.

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