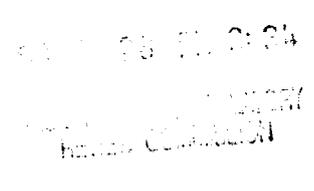


Regulatory Analysis Form		This space for use by IRRC
(1) Agency Department of Environmental Protection		 Josh IRRC Number: 1948
(2) I.D. Number (Governor's Office Use) 7-337		
(3) Short Title Bottled Water Systems: Permit by Rule		
(4) PA Code Cite 25 Pa Code Chapter 109	(5) Agency Contacts & Telephone Numbers Primary Contact: Sharon Freeman, 783-1303 Secondary Contact: Barbara Sexton, 783-1303	
(6) Type of Rulemaking (Check One) <input checked="" type="checkbox"/> Proposed Rulemaking <input type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Final Order, Proposed Rulemaking Omitted	(7) Is a 120-Day Emergency Certification Attached? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: By the Attorney General <input type="checkbox"/> Yes: By the Governor	
(8) Briefly explain the regulation in clear and nontechnical language. <p>The proposed amendments will establish a permit by rule for Pennsylvania permitted bottled water systems meeting specified criteria, reduce compliance monitoring requirements for radionuclides for bottled water systems, retail water facilities and bulk water hauling systems, allow label information on the caps of returnable bottles and allow submission of new or additional proprietary labels within 10 days following production of the new or additional label bottled water product. Other amendments are also included pertaining to coliform monitoring siting plan submission deadline which applies to all public water systems and clarifying the lead and cadmium compliance monitoring which applies to consecutive water systems.</p>		
(9) State the statutory authority for the regulation and any relevant state or federal court decisions. <p>Section 4 of the Pennsylvania Safe Drinking Water Act of May 1, 1984 (P.L. 206, No. 43), 35 P.S. §721.4 and Section 1920-A of the Administrative Code of 1929, 71 P.S. §510-20</p>		

Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

This amendment is not mandated by any federal or state law or court order or federal regulation. The proposed permit by rule is part of the PRIME (Privatize, Retain, Innovate, Modify and Eliminate) Initiative to provide better services to the regulated community and make government smaller, more efficient and responsive. Some amendments updated or clarified present requirements while others addressed issues determined through the Regulatory Basics Initiative (RBI) which identified regulations for possible revision that were obsolete, prescriptive, redundant, needing clarification or more stringent than federal regulations.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Pennsylvania bottlers have expressed concerns over the time and expense involved in obtaining permit amendments and the types of in-plant modifications which require permit amendments. The primary reason was that the requirements are affecting their ability to implement timely business decisions in responding to the bottled water market conditions. The proposed permit by rule would streamline the permitting process for modifications (such as addition of a new product or replacement of equipment) to the bottling, processing and manufacturing of bottled drinking water, result in more efficient and effective use of Department field staff and increase Pennsylvania bottlers' competitiveness with out of state bottlers.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Not applicable. Under Act 43, the Pennsylvania Safe Drinking Water Act, bottled water systems are regulated as public water systems.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Pennsylvania bottlers will benefit by having an option to obtaining a permit amendment from the Department for the construction or installation of substantial modifications (such as a new product line or replacement of equipment) to the bottling facilities. Under the permit by rule, Pennsylvania bottlers would not have to pay the \$300 - \$750 application fee for permit amendment applications. The permit by rule will provide Pennsylvania bottlers greater flexibility and opportunity to respond to market conditions and increase competitiveness with out-of-state bottlers. The consumers of bottled water may also benefit from lower prices. However, this is difficult to quantify due to the many factors involved in producing bottled water products which affect the retail price.

All bottled water systems, retail water facilities and bulk water hauling systems will benefit from the reduced radionuclide compliance monitoring from annually to once every four years.

Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effect as completely as possible and approximate the number of people who will be adversely affected.)

The proposed amendments are not expected to produce any adverse impacts.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

The proposed permit by rule is an option and any Pennsylvania bottler who qualifies is not required to operate under the permit by rule. All bottled water systems, retail water facilities and bulk water hauling systems are required to comply with the reduced radionuclide compliance monitoring. All public water systems would be required to comply with the 30 day submission deadline for identifying coliform monitoring sites.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The framework for the permit by rule was developed by a Workgroup consisting of representatives of several Pennsylvania bottlers, the International Bottled Water Association (IBWA), NSF International, a large tap water system, an engineering/consulting firm and the League of Women Voters as well as the Department and the Departments of Health and Agriculture. A draft version of the proposed amendments was reviewed by the Water Resources Advisory Committee (WRAC) at their November 12, 1997 meeting and by the Advisory Board for the Small Systems Technical Assistance Center (TAC) at their November 18, 1997 meeting. WRAC's comments and recommendations were evaluated in revising the draft amendments. The draft version was also placed on the Department's Web site.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

Under the permit by rule option, there would be an annual cost estimated at \$600-\$800 for the third party evaluation. Pennsylvania bottlers who are IBWA members or NSF certified should not experience an annual cost for the third party inspection since this cost is included in the membership fee or NSF's certification fee. The evaluation cost should be offset for all Pennsylvania bottlers operating under the permit by rule since the bottler would not be required to pay the application fee of \$300 - \$750 for major amendments to the bottling process under the present permitting procedures and the savings from the reduction in the radionuclide compliance monitoring. Since the permit by rule is an option, it is difficult to estimate the costs and/or savings to Pennsylvania bottlers. However, Pennsylvania bottlers operating under the permit by rule should realize time and cost savings from the streamlined permitting process by being able to implement timely business decisions such as installation of a new or additional production line without first waiting for a Department permit amendment. Pennsylvania bottlers would first notify the Department of the intent to operate under the permit by rule, file descriptions of substantial modifications within 30 days of operation of the modification and submit annual proof of compliance with the FDA standards based on the third party evaluation. It is not anticipated there will be any additional legal, accounting or consulting procedures from the proposed amendments. There will be a savings to the regulated community from the reduction of the radionuclide monitoring from annually to once every four years which is estimated at around \$ 37,000 over a four year period.

Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

The permit by rule option would apply to over 40 in-state Pennsylvania bottled water systems. The proposed amendments pertaining to submitting new or additional product labels and allowing labeling information on the cap of returnable bottles apply to almost 90 in-state and out-of state bottled water systems. These systems, for the most part, are privately owned businesses and there should be no additional costs imposed on local government.

The amendments pertaining to updating the coliform siting plans submission deadline which apply to all public water systems and clarifying the consecutive water systems monitoring for lead and cadmium should not have any impact on local government.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting or consulting procedures which may be required.

There should not be any additional costs to state government resulting from the amendments. Additional Department staff will not be needed to implement these amendments. However, there may be insignificant revenue losses since the permit by rule would not have any associated fees compared to a major permit amendment which requires an application fee of \$300 - \$750. Generally, less than 10 permit amendments per year are issued to in-state bottlers. However, any revenue loss resulting from the permit by rule should be outweighed by the increased efficiency and time and cost savings to the Department from eliminating the technical review of permit amendment applications and annual inspections of bottling facilities for those bottlers operating under the permit by rule. The costs and/or savings to state government cannot be determined since it depends on the number of in-state bottlers who would operate under the permit by rule and the number of modifications to the bottling facilities made each year.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and cost associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	0	12,600	12,600	12,600	0	12,600
Local Government	NA	NA	NA	NA	NA	NA
State Government	0	*	*	*	*	*
Total Savings	0	12,600	12,600	12,600	0	12,600
COSTS:						
Regulated Community	0	*	*	*	*	*
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	0	*	*	*	*	*
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	*	*	*	*	*
Total Revenue Losses	0	*	*	*	*	*

(20a) Explain how the cost estimates listed above were derived.

Over 90 bottled water and bulk water hauling systems use around 90 groundwater sources (wells and springs) of supply. The annual cost of radionuclide compliance monitoring was estimated as follows:

Gross alpha: 90 samples @ \$ 40/sample = \$ 3,600 per year
 Radium226 : 45 samples @ \$100/sample = \$ 4,500 per year
 Radium228 : 45 samples @ \$100/sample = \$ 4,500 per year
 Total = \$12,600 per year

Since the radionuclide compliance monitoring would be reduced from annually to once every four years, the cost savings would be \$12,600 for each of three years and the cost would be \$12,600 for the last year of a four year period.

* Since the permit by rule is an option and not a mandate, additional costs or savings to Pennsylvania bottlers and revenue losses and savings to state government could not be quantified. See Responses to Questions #17 and #19.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY-3	FY-2	FY-1	Current FY
Safe Drinking Water	4,945,663	5,291,226	5,595,129	6,304,000

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There should not be any adverse effects. Overall, the benefits will outweigh the costs as there will be no apparent significant additional costs on state and local governments. The proposed permit by rule option should result in cost savings to Pennsylvania bottlers by allowing the bottlers to implement timely business decisions (such as addition of a new production line) to respond to bottled water market demands faster than if required to first obtain a permit amendment from the Department. Consumers may also benefit from reduced prices for bottled water products. However, these are difficult to quantify because of the many factors involved in producing bottled water. Bottled water systems, retail water facilities and bulk water hauling systems will benefit from the reduction in the compliance monitoring for radionuclides from annually to once every four years.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Nonregulatory options to the permit by rule were not considered. Under the act, bottled water systems are regulated as public water systems subject to the permitting requirements of the act. Nonregulatory options were not considered for the radionuclide monitoring and the coliform siting plan submission since these are required by federal regulations. Generally, the remaining amendments clarify, update and modify the present requirements.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

Other regulatory alternatives considered included clarifying the types of in plant modifications requiring permit amendments, centralized permitting of in-state bottled water systems and privatizing the oversight of the bottling operations through a mandated third party evaluation. However, these did not completely address the concerns or needs of Pennsylvania's bottled water industry and/or would result in an increased regulatory compliance cost.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

The proposed amendments do not contain any provisions that are more stringent than federal standards.

(25) How does the regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This varies depending on the state. Some states require approvals or permits while other states simply require an annual fee for distribution of bottled drinking water. Overall, the permit by rule should increase the competitiveness of Pennsylvania bottlers against out-of-state bottlers.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The regulations being amended are 25 Pa Code §109.1, §109.301, §109.701, §109.1003, §109.1005, §109.1007 and §109.1008. The proposed amendments will not affect any other existing or proposed regulations of the Department or other state agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

None.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

Compared to obtaining a permit amendment under the present process, the proposed permit by rule option should reduce the paperwork requirements. Pennsylvania bottlers would first notify the Department of the intent to operate under the permit by rule, file descriptions of substantial modifications within 30 days of operation of the modification and submit annual proof of compliance with the FDA standards based on the third party evaluation. Bottlers operating under the permit by rule would still be required to comply with the other provisions of the act and regulations including design, construction, operation, reporting and recordkeeping. The other amendments should not have any major impact on existing reporting, recordkeeping or other paperwork requirements. The reduction in radionuclide monitoring would reduce reporting and paperwork requirements for bottled water systems, retail water facilities and bulk water hauling systems.

The amendments will require revisions to the technical guidance to field staff and other documents such as the Key Requirements Summary for Bottled, Vended Retail and Bulk Water Hauling Systems.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The proposed permit by rule option addresses the special needs of Pennsylvania's bottled water industry.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final rulemaking.

(31) Provide the schedule for continual review of the regulation.

The regulation will be reviewed in accordance with the sunset review schedule published by the Department.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

[Signature]
DEPUTY ATTORNEY GENERAL

APR 14 1998

DATE OF APPROVAL

Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-337

DATE OF ADOPTION:

BY: *[Signature]*

TITLE: JAMES M. SEIF, CHAIRMAN
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is hereby approved as to form and legality. Executive or Independent Agency

[Signature]
BY:

3/18/98

DATE OF APPROVAL

(Deputy General Counsel)
(Chief Counsel, Independent Agency)
(Strike inapplicable title)

Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF
PROPOSED RULEMAKING
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

BOTTLED WATER SYSTEMS: PERMIT BY RULE

25 PA CODE CHAPTER 109

Notice of Proposed Rulemaking
Department of Environmental Protection
Environmental Quality Board
(25 Pa. Code, Chapter 109)
(Safe Drinking Water)

Preamble

The Environmental Quality Board (Board) proposes to amend 25 Pa. Code, Chapter 109 (relating to Safe Drinking Water). The amendments would establish a permit by rule for in-state permitted bottled water systems that meet certain specified criteria, reduce compliance monitoring for radionuclides for bottled water systems, retail water facilities and bulk water hauling systems, allow label information on the cap of returnable containers and allow new or additional proprietary labels to be submitted to the Department following production or distribution of the new or additional label product. Other minor revisions are also included pertaining to the submission of the coliform monitoring siting plan applicable to all public water systems and clarifying consecutive water system monitoring for lead and cadmium.

This proposal was adopted by the Board at its meeting of March 17, 1998.

A. Effective Date

These amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. Contact Persons

For further information contact Frederick Marrocco, Acting Director, Bureau of Water Supply Management, P.O. Box 8467, Rachel Carson State Office Building, Harrisburg, PA 17105-8467, (717) 787-9035 or Pamela Bishop, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Information regarding submitting comments on this proposal appears in Section I of this preamble. Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users). This proposal is available electronically through the DEP Web site (<http://www.dep.state.pa.us>).

C. Statutory Authority

The proposed rulemaking is being made under the authority of Section 4 of the Pennsylvania Safe Drinking Water Act (act) (35 P.S. § 721.4), which grants the Board the authority to adopt rules and regulations governing the provision of drinking water to the public and Sections 1917-A and 1920-A of the Administrative Code of 1929 (71 P.S. §510-7 and §510-20).

D. Background and Purpose

The act authorizes the Department to regulate public water systems in this Commonwealth. The act defines "public water system" to include "a system which provides water for bottling or bulk hauling for human consumption."

Systems providing water for bottling include:

- (1) Bottled water systems, which provide water for bottling in sealed containers.
- (2) Vended water systems, which provide water for bottling through the use of water vending machines.
- (3) Retail water facilities which provide water for bottling by dispensing, at a store counter, unit servings of water in a customer's or the system's containers.

Beginning in December 1984, the overall requirements in Chapter 109 pertaining to these water systems became effective. Chapter 109 was amended in May 1992 (20 Pa.B 2621) to place all requirements pertaining to these types of systems in one subchapter rather than having the requirements interspersed among requirements for other public water systems throughout Chapter 109.

Representatives of the large in-state bottled drinking water operations have expressed concerns over the time and expense involved in obtaining permit amendments and the types of in-plant modifications which require permit amendments. The primary reason for the concern was that the requirements were affecting their ability to implement timely business decisions. In response, a workgroup was formed consisting of several Pennsylvania bottlers, the International Bottled Water Association (IBWA), NSF *International* (NSF), representatives of a large tap water system, an engineering/consulting firm and the League of Women Voters in addition to representatives of the Department and the Departments of Agriculture and Health. The purpose of the workgroup was to develop a framework for a permit by rule for bottled water systems to streamline the permitting process and minimize business disruption while ensuring regulatory efficiency, compliance and protection of public health. This is part of the Governor's PRIME (Privatize, Retain, Innovate, Modify and Eliminate) Initiative to provide better services to the regulated community and to make government smaller, more efficient and responsive.

Bottled water is regulated at the federal level as a food product by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq. The federal requirements applicable to bottled water include: food adulteration and misbranding provisions of federal law; general food and specific bottled water Good Manufacturing Practice (GMP) regulations; standards of identity and quality for bottled water; and both civil and criminal penalties for non-compliance with the above-mentioned FDA requirements. Pennsylvania's existing regulations require compliance with the provisions of FDA requirements under 21 CFR 129 relating to processing and bottling of bottled water.

The IBWA is the trade organization for the bottled water industry. In addition to the FDA requirements, IBWA's Model Bottled Water Code for IBWA members provides information and standards on bottled water manufacturing practices, operational requirements and quality control for the bottled water industry.

NSF is an internationally recognized third party inspection and certification agency. NSF's bottled water certification program verifies that a bottling facility and product waters meets the requirements of the federal FDA regulations governing bottled water. NSF conducts an annual unannounced audit of the bottling and processing facilities including source/product water testing. Bottlers meeting the certification requirements are allowed to use the registered NSF listing mark in their advertising, promotional activities and product listing. IBWA members have an annual unannounced on-site audit conducted by NSF; however, NSF certification is not a requirement of IBWA membership.

The Bottled Water workgroup met on several occasions resulting in the cooperative development of a proposed permit by rule framework for in-state bottlers which addresses the bottled water industry concerns.

The permit by rule proposal would provide in-state permitted bottlers an option to obtaining a permit amendment for substantial modifications (except for the addition of new sources or expanded use of existing permitted sources) to the bottling, processing or manufacturing facilities provided certain specified criteria are met. Specific criteria would include: the source type (ground water not under the direct influence of surface water and/or finished water from a community water system); the source water quality (does not exceed FDA quality standards for health related chemical and radiological contaminants and requires only disinfection to meet the Pennsylvania primary maximum contaminant levels); use of acceptable treatment technologies; and demonstrated compliance with the national standards of the FDA and the IBWA Model Bottled Water Code as determined by an annual on-site evaluation conducted by a third party organization such as NSF. The bottler would first notify the Department of the intent to operate under the permit by rule. A bottled water system operating under the permit by rule would file with the Department descriptions of substantial modifications such as replacement of equipment or addition of a new product line within 30 days of operation of the modification.

New in-state bottled water systems would still be required to obtain a public water system permit for the construction and operation of the bottled water system after which they could operate under the permit by rule option if qualified. The permit by rule does not include new sources or expanded use of existing permitted sources which would continue to require a permit amendment from the Department under the present permitting requirements. Any bottler seeking to use the permit by rule would have to comply with all other applicable laws administered by the Department as required by Section 7 of the Safe Drinking Water Act and comply with other requirements of Chapter 109 (relating to Safe Drinking Water) regulations including design, construction, operation, monitoring and reporting.

The draft proposed permit by rule was presented to the Water Resources Advisory Committee (WRAC) at its November 12, 1997 meeting and to the Advisory Board for the Small Systems Technical Assistance Center (TAC) at its November 18, 1997 meeting. The TAC Board approved the proposed amendments. WRAC's review and recommendations resulted in the following changes to the draft proposal:

1. Deletion of IBWA from the authority to determine the acceptability of the third party inspection organization in § 109.1005(c)(3) so that only the Department determines the acceptability of the third party evaluation organization.

2. Deletion of “operationally” in § 109.1005(c)(3)(i) since it infers that the third party inspection organization is involved with operating a bottled water system.

3. Addition of a new § 109.1005(c)(3)(v) pertaining to the evaluation organization demonstrating the capability through experience and/or training to implement and conduct the on-site evaluation.

The WRAC also recommended that § 109.1005(c)(5) be changed to require the bottler to notify the Department of substantial modifications to the system “...from 30 days following operation of the modification...” to “...at least 30 days prior to the operation of the modification...” One of the purposes of developing a permit by rule was to streamline the permitting process. The recommendation would require the bottler to determine in advance what substantial modifications (including replacement of existing equipment) would be required and would not authorize operation of the modification within the 30 day period. This could result in a delay in resuming production which would be costly to the bottler and result in possible loss of market share. The Department believes the proposed 30 days notice following operation is appropriate and does not preclude the bottler from submitting the information in advance of the operation of the proposed facilities.

The proposed amendments pertaining to radionuclide compliance monitoring, labeling requirements for returnable containers and coliform monitoring site plan submission address issues determined through the Regulatory Basics Initiative (RBI) which identified regulations for possible revision that were obsolete, prescriptive, redundant, needing clarification or more stringent than federal regulations.

The average daily consumption of drinking water is assumed to be two liters per person per day in establishing drinking water standards. Because a container smaller than a half gallon cannot provide one person’s drinking water needs for one day, the Department, by policy published in the Preamble to the May 16, 1992 revisions (20 Pa.B 2621) to Chapter 109, announced its intention to regulate only those bottled water systems providing water for bottling in one-half gallon or larger containers. Many specialized bottled water products are marketed as beverages or pharmaceuticals, and generally in small containers. The Department has not regulated such products which are generally regulated under State and Federal Food and drug laws. Consumers’ demands for more convenience in bottled drinking water has led to an increase in the small bottled water product market. Bottlers who bottle the large containers also use the same water in bottling in the small containers. There may be bottlers who only produce the smaller sizes for distribution in Pennsylvania and thus are not regulated under the Department’s safe drinking water regulations.

As part of this proposed rulemaking, the Department is requesting comment with supporting data on whether it should modify its policy on regulating small bottled products (less than one half gallon) and bottlers of small bottled products.

E. Summary of Regulatory Requirements

1. Section 109.1. *Definitions*. Added definition for IBWA, the International Bottled Water Association and revised the definition for NSF to reflect the new name of NSF *International*.

2. Section 109.301(8). *Consecutive water system monitoring for lead and cadmium*. Subparagraph (B) was deleted, subparagraph (C) was renumbered as (B) and references to lead and cadmium monitoring in subparagraph (iii) were deleted. The current regulations are confusing in that consecutive systems under subparagraph (iii) are required to monitor for lead and cadmium in accordance with subparagraph (ii)(B) which was reserved. The intent of the Department was to delete the lead and cadmium monitoring requirement in subparagraph (iii). Consecutive systems are required to monitor for lead under Section 109.1101(c). Cadmium is a contaminant in the metals used to galvanize pipe and in brass used in faucets and generally gets into finished water by corrosion of galvanized pipes or into the source water by improper waste disposal. Compliance monitoring for cadmium is required at the entry point to the distribution system. Since corrosion control measures to meet the lead action level would also minimize the corrosion of cadmium from galvanized pipe and brass faucets, the lead and cadmium monitoring requirements in subparagraph (iii) are unnecessary.

3. Section 109.701(a)(5) *Siting Plan*. The "...November 16, 1992..." date was deleted and replaced with "...within 30 days of receipt of the Department's request for this information" for submission of a siting plan for coliform monitoring. The present requirement was identified under the Regulatory Basics Initiative as obsolete.

4. Section 109.1003(a)(1)(vii). *General monitoring requirements*. The monitoring for compliance with radiological maximum contaminant levels (MCLs) for bottled water systems, retail water facilities and bulk water hauling systems was reduced from "...annually..." to "...once every four years..." The present requirement was identified under the Regulatory Basics Initiative as more stringent than the federal requirements.

5. Section 109.1005. *Permit requirements*. A new subsection (c) *Special permit by rule requirement for bottled water systems* was added. The proposed subsection would provide an option for in-state permitted bottlers to obtain a permit amendment for modifications (except for the addition of new sources or expanded use of existing permitted sources) to the bottling, processing or manufacturing facilities provided the bottled water system meets certain specified criteria. Specific criteria would include the source type (ground water not under the direct influence of surface water and/or finished water from a community water system) and water quality (does not exceed FDA quality standards for health related chemical and radiological contaminants and requires only disinfection to meet the Pennsylvania primary maximum contaminant levels), use of acceptable treatment technologies and demonstrated compliance with the national standards of the FDA and the IBWA Model Bottled Water Code as determined by an annual on-site evaluation conducted by a third party organization such as NSF or other organizations acceptable to the Department. To be acceptable to the Department, the organization must be independent of the bottlers using its services, have policies and procedures indicating the organization will support the Department's enforcement actions, have a system to respond to bottlers' complaints with appropriate due process safeguards, maintain a quality assurance and quality control program, and demonstrate its capability to conduct an on-site evaluation program. The bottler would be required to notify the Department of the intent to operate under the permit by rule and would notify the Department within 30 days following operation of a substantial modification to the bottling, processing or manufacturing facilities for the bottled water products.

6. Section 109.1007(a). *General Labeling requirements*. The present regulation requires containers of bottled water to have labels which are designed to remain affixed to the container during usage. Through guidance, the Department has included the cap on returnable bottles under the "...affixed to the container during use..." in subsection (a). The present requirements were identified under the Regulatory Basics Initiative as being unclear. The proposed amendments reflect the guidance.

7. Section 109.1008(a)(3). *Reporting and recordkeeping requirements for bottled water and vended water systems, retail water facilities and bulk water hauling systems*. Bottlers are now required to submit new or proprietary labels to the Department for approval prior to beginning production of the new bottled water product. Subparagraph (a)(3) has been revised to require the bottler to submit new or proprietary labels to the Department within 10 days following the production or distribution of the new or additional bottled water product. The bottler can also submit the new or additional labels to the Department in advance for a Department review if desired. The bottler will still be required to comply with the provisions of Section 109.1007 (relating to labeling requirement for bottled water systems, vended water systems and retail water facilities).

F. Benefits, Costs and Compliance

Executive Order 1996-1 requires a cost/benefit analysis of the proposed regulation.

Benefits

Pennsylvania bottlers who elect to operate under the permit by rule should realize time and cost savings from the streamlined permitting process by being able to make timely business decisions such as installation of a new or additional production line or replacement equipment without first obtaining a Department permit amendment. Along with the revised requirements for submitting new or additional product labels, this will provide Pennsylvania bottlers greater flexibility and opportunity to respond to market conditions and increase competitiveness with out-of-state bottlers. The consumers of bottled water may also benefit from lower prices; however, this is difficult to quantify, due to the many factors affecting the retail price in producing bottled water products.

Over 90 bottled water systems, retail water facilities and bulk water hauling systems will benefit from the reduction in the compliance monitoring for radionuclides from annually to once every four years.

Compliance Costs

There should be no additional costs to state and local government or the regulated community to implement the proposed amendments.

The permit by rule is an option and any Pennsylvania bottler is not required to operate under the permit by rule. Under the permit by rule option, there would be an annual cost estimated at \$600-\$800 for the third party evaluation. Pennsylvania bottlers who are IBWA members or NSF certified should not experience an annual cost for the third party inspection since this cost is included in IBWA's membership fee or NSF's certification fee. Pennsylvania bottlers who do not have an annual third party evaluation and elect to operate under the permit by rule would experience the annual

evaluation cost. However, this cost should be offset by the bottler not being required to pay a permit application fee of \$300 to \$750 for major amendments to the bottling process under the present permitting procedures and the cost savings from reducing the radionuclide compliance monitoring from annually to once every four years. Since the permit by rule is an option, it is difficult to estimate the additional costs (if any) to Pennsylvania bottlers.

Compliance Assistance Plan

It is anticipated that extensive compliance assistance will not be necessary. The permit by rule is an option for Pennsylvania bottlers. The other proposed amendments update, modify or clarify present requirements.

The Department will notify the regulated community through the Environmental Protection Update Weekly Newsletter and through revised Key Requirements summaries affected by the proposed amendments. The Key Requirements summaries are available to the regulated community and placed on the Department's Web Site. If necessary, the Department will directly notify the regulated community, including out-of-state bottlers, through mailings. Department staff will be available to assist the regulated community and any Pennsylvania bottler considering operating under the permit by rule.

Paperwork Requirements

There should be no increase in the amount of paperwork. Overall, with the exception of the permit by rule, the proposed amendments update, clarify or revise present requirements and should not have any major impact on existing reporting, recordkeeping or other paperwork requirements.

Compared to obtaining a permit amendment under the present permitting process, Pennsylvania bottlers would first notify the Department of the intent to operate under the permit by rule, file descriptions of substantial modifications within 30 days of operation of the modification and submit annual proof of compliance with the FDA standards and the IBWA Model Bottled Water Code based on the third party evaluation. Bottlers operating under the permit by rule would still be required to comply with the other provisions of the act and regulations including design, construction, operation, reporting and recordkeeping. The Department anticipates the permit by rule would decrease paperwork requirements compared to obtaining a Department permit for modifications to the bottling, processing and manufacturing of bottled water. The reduction in radionuclide monitoring would reduce reporting and paperwork requirements for over 90 bottled water systems, retail water facilities and bulk water hauling systems.

G. Sunset Review

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

H. Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)), the Department submitted a copy of the proposed rulemaking on April 28, 1998, to the Independent Regulatory Review Commission (IRRC), and the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed regulatory analysis form prepared by the Department. A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed amendments, it will notify the Department within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review by the Department, the Governor, and the General Assembly before final publication of the regulation.

I. Public Comments

Written Comments - Interested persons are invited to submit comments, suggestions, or objection regarding the proposed regulation to the Environmental Quality Board, P.O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by June 8, 1998 (within 30 days of publication in the *Pennsylvania Bulletin*). Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by June 8, 1998 (within 30 days of publication in the *Pennsylvania Bulletin*). The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulations will be considered.

Electronic Comments - Comments may be submitted electronically to the Board at RegComments@A1.dep.state.pa.us and must also be received by the Board by June 8, 1998. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgment of electronic comments is not received by the sender within two working days, the comments should be retransmitted to ensure receipt.

BY:

JAMES M. SEIF
Chairman
Environmental Quality Board

Annex A

Title 25. ENVIRONMENTAL RESOURCES

**PART I. DEPARTMENT OF
ENVIRONMENTAL PROTECTION**

CHAPTER 109. SAFE DRINKING WATER

Subchapter A. GENERAL PROVISIONS

§ 109.1. Definitions.

* * * * *

IBWA - THE INTERNATIONAL BOTTLED WATER ASSOCIATION, ALEXANDRIA, VA

22314.

* * * * *

NSF - [The National Sanitation Foundation] NSF INTERNATIONAL, Ann Arbor, Michigan 48105.

* * * * *

Subchapter C. MONITORING REQUIREMENTS

§ 109.301. General monitoring requirements.

* * * * *

(8) Monitoring requirements for public water systems that obtain finished water from another public water system.

* * * * *

(ii) Community consecutive water suppliers shall:

(A) Monitor for compliance with the MCL for total trihalomethanes (TTHMs) at the frequency established by the EPA and incorporated by reference into this chapter if the system does one of the following:

(I) Serves more than 10,000 persons.

(II) Obtains finished water from another public water system serving more than 10,000 persons.

[(B) [Reserved]]

[(C)] (B) Monitor the distribution system for compliance with the MCL for asbestos at the frequency indicated in paragraph (7)(i), when the Department determines that the system's distribution system contains asbestos cement pipe and optimum corrosion control measures have not been implemented.

(iii) Consecutive water suppliers are exempt from conducting monitoring for the MCLs for VOCs, SOCs and IOCs if the public water system from which the finished water is obtained complies with paragraphs (5)--(7), except that [lead and cadmium monitoring is required in accordance with subparagraph (ii)(B), and] asbestos monitoring is required in accordance with subparagraph [(ii)(C)] (ii)(B).

* * * * *

Subchapter G. SYSTEM MANAGEMENT RESPONSIBILITIES

§ 109.701. Reporting and recordkeeping.

(a) *Reporting requirements for public water systems.* Public water systems shall comply with the following requirements:

* * * * *

(5) *Siting plan.* The water supplier shall submit to the Department a written sample siting plan for routine coliform sampling as required by § 109.303(a)(2) [by November 16, 1992] WITHIN 30 DAYS OF RECEIPT OF THE DEPARTMENT'S REQUEST FOR THIS INFORMATION.

* * * * *

Subchapter J. BOTTLED WATER AND VENDED WATER SYSTEMS,
RETAIL WATER FACILITIES AND BULK WATER HAULING SYSTEMS

§ 109.1003. Monitoring requirements.

(a) *General monitoring requirements.* Bottled water and vended water systems, retail water facilities and bulk water hauling systems shall monitor for compliance with the MCLs in accordance with the requirements under § 109.301 (relating to general monitoring requirements) and shall comply with § 109.302 (relating to special monitoring requirements). The monitoring requirements shall be applied as follows, except that systems which have installed treatment to comply with a primary MCL shall conduct quarterly operational monitoring for the contaminant which the facility is designed to remove:

(1) Bottled water systems, retail water facilities and bulk water hauling systems, for each entry point shall:

* * * * *

(vii) Monitor for compliance with radiological MCLs [annually] ONCE EVERY FOUR YEARS.

* * * * *

§ 109.1005. Permit Requirements.

* * * * *

(c) SPECIAL PERMIT BY RULE REQUIREMENT FOR BOTTLED WATER SYSTEMS. A PERSON OWNING OR OPERATING A BOTTLED WATER SYSTEM IN PENNSYLVANIA PERMITTED UNDER THIS CHAPTER SHALL OBTAIN AN AMENDED PERMIT BEFORE MAKING SUBSTANTIAL MODIFICATIONS TO THE PROCESSING AND BOTTLING FACILITIES UNLESS THE BOTTLED WATER SYSTEM SATISFIES THE CONDITIONS FOR A PERMIT BY RULE IN PARAGRAPHS (1) - (5). THE PERMIT BY RULE DOES NOT APPLY TO THE ADDITION OF NEW SOURCES OR THE EXPANDED USE OF EXISTING PERMITTED SOURCES USED BY THE BOTTLED WATER SYSTEM. FOR THE ADDITION OF NEW SOURCES OR THE EXPANDED USE OF EXISTING PERMITTED SOURCES, A PERMIT AMENDMENT UNDER SUBSECTION (f) (RELATING TO PERMIT AMENDMENT APPLICATIONS) MUST BE OBTAINED. THE DEPARTMENT RETAINS THE RIGHT TO REQUIRE A BOTTLED WATER SYSTEM THAT MEETS THE REQUIREMENTS OF PARAGRAPHS (1) - (5) TO OBTAIN A PERMIT, IF, IN THE JUDGMENT OF THE DEPARTMENT, THE BOTTLED WATER SYSTEM CANNOT BE ADEQUATELY REGULATED THROUGH THE STANDARDIZED SPECIFICATIONS AND CONDITIONS. A BOTTLED WATER SYSTEM WHICH IS RELEASED FROM THE OBLIGATION TO OBTAIN A PERMIT SHALL COMPLY WITH THE OTHER REQUIREMENTS OF THIS SUBCHAPTER, INCLUDING DESIGN, CONSTRUCTION AND OPERATION REQUIREMENTS.

(1) THE BOTTLED WATER SYSTEM HAVING AS ITS SOLE SOURCE OR SOURCES OF WATER PERMITTED GROUNDWATER SOURCES WHICH ARE NOT UNDER THE DIRECT INFLUENCE OF SURFACE WATER AS DETERMINED THROUGH A PROTOCOL ESTABLISHED BY THE DEPARTMENT OR APPROVED BY THE DEPARTMENT AND/OR FINISHED WATER FROM A DEPARTMENT APPROVED COMMUNITY WATER SYSTEM.

(2) THE WATER QUALITY OF THE SOURCE OR SOURCES DOES NOT EXCEED THE FOOD AND DRUG ADMINISTRATION QUALITY STANDARDS FOR PRIMARY (I.E. HEALTH-RELATED) CHEMICAL AND RADIOLOGICAL CONTAMINANTS SPECIFIED IN 21 CFR PART 165.110 (RELATING TO BEVERAGES) AS DETERMINED UNDER SAMPLING CONDUCTED UNDER SUBSECTION (e)(4)(ii) AND REQUIRES TREATMENT NO GREATER THAN DISINFECTION TO PROVIDE WATER OF A QUALITY THAT MEETS THE PRIMARY MCLs ESTABLISHED UNDER SUBCHAPTER B (RELATING TO MCLs AND TREATMENT TECHNIQUES).

(3) PROOF THAT THE FACILITIES MEET THE PROVISIONS OF THE STANDARDS OF THE FOOD AND DRUG ADMINISTRATION REGULATIONS IN 21 CFR PART 129 (RELATING TO CURRENT GOOD MANUFACTURING PRACTICES), 21 CFR PART 110 (RELATING TO PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER) AND 21 CFR PART 165 (RELATING TO BEVERAGES) AND THE IBWA MODEL BOTTLED WATER CODE AS DETERMINED BY AN ON-SITE EVALUATION CONDUCTED BY A NATIONALLY RECOGNIZED, INDEPENDENT, NOT-FOR-PROFIT THIRD PARTY ORGANIZATION SUCH AS NSF OR OTHER ORGANIZATION ACCEPTABLE TO THE

DEPARTMENT. THE ON-SITE EVALUATION SHALL BE CONDUCTED ANNUALLY. THE PROOF SHALL CONSIST OF THE REPORT ISSUED BY THE ORGANIZATION WHICH SHALL BE SUBMITTED TO THE DEPARTMENT WITHIN 30 DAYS FOLLOWING THE COMPLETION OF THE ON-SITE EVALUATION. TO BE ACCEPTABLE TO THE DEPARTMENT, THE ORGANIZATION SHALL:

(i) DEMONSTRATE IT IS INDEPENDENT OF THE BOTTLED WATER SYSTEMS USING THE ORGANIZATION'S SERVICES.

(ii) HAVE WELL DEVELOPED, DOCUMENTED POLICIES, PROCEDURES, AND CONTRACTS TO SUPPORT ENFORCEMENT ACTIONS FOR MEETING COMPLIANCE OBJECTIVES.

(iii) HAVE AN ESTABLISHED SYSTEM FOR INVESTIGATING COMPLAINTS AND TAKING APPROPRIATE ACTIONS, WITH AN EFFECTIVE APPEALS PROCESS.

(iv) MAINTAIN A DOCUMENTED ONGOING QUALITY ASSURANCE AND QUALITY CONTROL PROGRAM

(v) DEMONSTRATE THE CAPABILITY THROUGH EXPERIENCE AND/OR TRAINING TO IMPLEMENT AND CONDUCT AN ON-SITE EVALUATION PROGRAM

(4) A BOTTLED WATER SYSTEM INTENDING TO OPERATE UNDER THIS SUBSECTION SHALL SUBMIT WRITTEN NOTIFICATION TO THE DEPARTMENT WITH DOCUMENTATION THAT THE SYSTEM COMPLIES WITH SUBPARAGRAPHS (1)-(3).

(5) A BOTTLED WATER SYSTEM OPERATING UNDER THIS SUBSECTION SHALL FILE DESCRIPTIONS OF SUBSTANTIAL MODIFICATIONS MADE TO THE SYSTEM TO THE DEPARTMENT WITHIN 30 DAYS OF OPERATION OF THE MODIFICATION. THE DESCRIPTION SHALL INCLUDE DOCUMENTATION THAT THE MODIFICATION MEETS THE FOLLOWING REQUIREMENTS AS APPLICABLE:

(i) COMPLIANCE WITH THE PRODUCT WATER-CONTACT MATERIALS AND TREATMENT CHEMICAL ADDITIVES TOXICOLOGICAL REQUIREMENTS OF § 109.606 (RELATING TO CHEMICALS, MATERIALS AND EQUIPMENT) OR ALTERNATIVELY, THE FOOD AND DRUG ADMINISTRATION STANDARDS IN 21 CFR PART 129 (RELATING TO PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER).

(ii) VALIDATED TREATMENT TECHNOLOGIES FOR THE REDUCTION OF CONTAMINANTS. VALIDATION MAY BE ESTABLISHED BY CERTIFICATION TO AN APPLICABLE ANSI/NSF STANDARD OR THROUGH PROTOCOLS DEVELOPED BY ORGANIZATIONS/CONSORTIA SUCH AS, BUT NOT LIMITED TO, NSF *INTERNATIONAL*, AMERICAN WATER WORKS ASSOCIATION RESEARCH FOUNDATION AND THE ENVIRONMENTAL PROTECTION AGENCY TECHNOLOGY VERIFICATION PROGRAM.

[(c)] (d) *Permit Amendments.* A person may not substantially modify a bottled water or vended water system, retail water facility or bulk water hauling system operated under a public water system permit without obtaining a permit amendment from the Department or otherwise complying with subsection [(e)] (f).

* * * * *

[(d)] (e) *Permit Applications.* An application for a public water system permit for a bottled water or vended water system, retail water facility or bulk water hauling system shall be submitted in writing on forms provided by the Department and shall be accompanied by plans, specifications, engineer's report, water quality analyses and other data, information or documentation reasonably necessary to enable the Department to determine compliance with the act and this chapter. The Department will make available to the applicant the Public Water Supply Manual, available from the Bureau of Water Supply [and Community Health] MANAGEMENT, Post Office Box 8467, Harrisburg, PA 17105-8467 which contains acceptable design standards and technical guidance. Water quality analyses shall be conducted by a laboratory certified under this chapter. An application for a public water system permit for a bottled water or vended water system, retail water facility or bulk water hauling system shall include:

* * * * *

[(e)] (f) *Permit amendment applications.* A bottled water or vended water system, retail water facility or bulk water hauling system operating under a public water system permit shall obtain a permit amendment before making a substantial modification to the public water system.

(1) A water supplier shall submit an application for a major permit amendment in accordance with subsection [(d)] (e), if the proposed modification constitutes a major change to the public water system.

* * * * *

(iii) For vended water systems, typical modifications which may be considered major changes are proposed additions or deletions of treatment techniques or processes, new product lines or types of products and the addition to the system of machines not certified by NAMA. For new sources, the supplier shall obtain a separate and distinct permit in accordance with subsection [(d)] (e) unless the system qualifies for a permit by rule under subsection (b).

* * * * *

(3) The Department determines whether a particular modification requires a permit amendment under subsection [(e)(1)] (f)(1) or a permit amendment under subsection [(e)(2)] (f)(2). The Department's determination will include consideration of the magnitude and complexity of the proposed change and the compliance history of the public water system.

[(f)] (g) *Emergency permits.* In emergency situations, the Department may issue permits for construction, operation or modification to a bottled water or bulk water hauling system, which the Department determines may be necessary to assure that potable drinking water is available to the public.

(1) Emergency permits shall be limited in duration and may be conditioned on additional monitoring, reporting and the implementation of appropriate emergency response measures. The Department may revoke an emergency permit if it finds the water system is not complying with drinking water standards or the terms or conditions of the permit. An authorization for construction, operation or modifications obtained under an emergency permit will not extend beyond the expiration of the emergency permit unless the public water system receives a permit or permit amendment under subsection [(d)] (e) or [(e)] (f) for the construction, operation or modification initiated during the emergency.

* * * * *

[(g)] (h) *Department's review.* Applications for public water system permits and permit amendments for bottled water and vended water systems, retail water facilities and bulk water hauling systems will be reviewed in accordance with the following procedures:

* * * * *

(3) As a condition of receiving a public water system permit, a bottled water system shall comply with the standards of the Food and Drug Administration contained in 21 CFR Part 129. Evidence shall be presented demonstrating compliance with subsection [(d)(7)(iii)] (e)(7)(iii).

* * * * *

[(h)] (i) *Permit fees.*

(1) An application for a new permit or major permit amendment under subsection [(e)(1)] (f)(1) for a bottled water or vended water system, retail water facility or bulk water hauling system shall be accompanied by a check in the amount of \$750 payable to the “Commonwealth of Pennsylvania,” except that:

(i) An application from an out-of-State bottled water system submitting proof of out-of-State approval under subsection [(d)(6)] (e)(6) shall be accompanied by a fee of \$100.

* * * * *

(2) A fee is not required for an emergency permit under subsection [(f)] (g) or a minor permit amendment under subsection [(e)(2)] (f)(2).

§109.1007. Labeling requirements for bottled water systems, vended water systems and retail water facilities.

(a) *General labeling requirements.* Containers of bottled water distributed in this Commonwealth by bottled water systems, retail water facilities or, when appropriate, vended water systems, shall have labels which are designed to remain affixed to the container during use and which include the following information[:] AS REQUIRED BY THIS SECTION. LABELS WITH THE FOLLOWING INFORMATION ON THE CAPS OF BOTTLED WATER CONTAINERS DESIGNED FOR REUSE BY THE BOTTLER ARE DEEMED TO MEET THIS REQUIREMENT PROVIDED THE

DEPARTMENT-ISSUED IDENTIFICATION NUMBER AND THE MANUFACTURE DATE,
LOT OR BATCH NUMBER ARE ON THE BOTTLE:

* * * * *

§ 109.1008. System management responsibilities.

(a) *Reporting and recordkeeping requirements for bottled water and vended water systems, retail water facilities and bulk water hauling systems.* Bottled water and vended water systems, retail water facilities and bulk water hauling systems shall comply with the reporting requirements in § 109.701(a) and (d) (relating to reporting and recordkeeping).

* * * * *

(3) For bottled water systems and, if applicable, vended water systems and retail water facilities, new or additional proprietary labels shall be reported to the Department in writing, along with copies of the labels, [at least] WITHIN 10 days [prior to commencing] FOLLOWING production or distribution of the new OR ADDITIONAL label product. THE NEW OR ADDITIONAL PROPRIETARY LABELS MAY BE SUBMITTED TO THE DEPARTMENT PRIOR TO THE PRODUCT PRODUCTION IF THE WATER SUPPLIER DESIRES INITIAL DEPARTMENT REVIEW. THE NEW OR ADDITIONAL PROPRIETARY LABELS SHALL COMPLY WITH THE PROVISIONS OF § 109.1007 (RELATING TO LABELING REQUIREMENTS FOR BOTTLED WATER SYSTEMS, VENDED WATER SYSTEMS AND RETAIL WATER FACILITIES).

(b) *Operation and maintenance plan requirements.* Bottled water, vended water, retail water and bulk water suppliers shall develop an operation and maintenance plan for each system. The operation and maintenance plan shall conform to the guidelines contained in Part III of the Department's Public Water Supply Manual which is available from the Bureau of Water Supply [and Community Health] MANAGEMENT, Post Office Box 8467, Harrisburg, Pennsylvania 17105. The water supplier shall implement the operation and maintenance plan in accordance with this chapter, and if appropriate in accordance with accepted practices of the bottled water, vended water, retail water facility or bulk water hauling industry. The plan shall be reviewed and updated as necessary to reflect changes in the operation or maintenance of the water system. The plan shall be bound and placed in locations which are readily accessible to the water system's personnel, and shall be presented upon request to the Department.

* * * * *



Pennsylvania Department of Environmental Protection

Rachel Carson State Office Building

P.O. Box 2063

Harrisburg, PA 17105-2063

April 28, 1998

The Secretary

**Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
Harrisburg, PA 17101**

RE: Proposed Rulemaking: Bottled Water Systems Permit by Rule (#7-337)

Dear Bob:

Enclosed is a copy of a proposed regulation for review by the Independent Regulatory Review Commission pursuant to the Regulatory Review Act. Section 5(b)(3) of the Act provides that the Commission shall have 30 calendar days from the closing date of the public comment period to notify the Department of any objections.

The Department of Environmental Protection will provide the Commission with any assistance it may require to facilitate the review of this proposed regulation. If you have any questions regarding this proposal, please contact Sharon Freeman, Regulatory Coordinator, at 783-1303.

Sincerely,

**James M. Seif
Secretary**

Enclosure

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

I.D. NUMBER: 7-337
 SUBJECT: *Bottled* ~~Boiled~~ Water Systems: Permit by Rule
 AGENCY: Department of Environmental Protection

RECEIVED
 APR 23 1998 11:34
 HOUSE OF REPRESENTATIVES
 REGULATORY REVIEW COMMISSION

TYPE OF REGULATION

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
<u>4/28/98</u>	<u>Gen. Comp</u>	HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
<i>George</i> <u>4/28/98</u>	<u>D. Newell</u>	
<u>4/28/98</u>	<u>Shawty G. Miller</u>	SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
^{MISS TO} <u>4/28/98</u>	<u>A. Reibarsch</u>	
<u>4/28/98</u>	<u>Kim C. Garner</u>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
<u>4/28/98</u>	<u>Cynthia J. Lee</u>	LEGISLATIVE REFERENCE BUREAU

April 23, 1998