CHAPTER I STATE SANITARY CODE

PART 5
DRINKING WATER SUPPLIES
(Statutory Authority: Public Health Law §225)

SUBPART 5-6
BOTTLED AND BULK WATER STANDARDS

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SUBPART 5-6

BOTTLED AND BULK WATER STANDARDS
(Statutory Authority: Public Health Law §225)

Section

5-6.1 Applicability. The provisions of sections 5-6.2 through 5-6.18 of this Subpart shall apply to bottled and bulk water produced, used and/or sold in New York State.

5-6.2 Distribution of bottled or bulk water. No person shall sell, offer for sale or deliver bottled or bulk water for human consumption, food preparation, or culinary purposes unless certified by the commissioner in accordance with the requirements of this Subpart.

5-6.3 Definitions. As used in this Subpart, the following words or terms shall have the indicated meaning, except as otherwise specifically provided:

(a) Approved laboratory shall mean a laboratory approved and certified by the New York State Department of Health's Environmental Laboratory Approval Program.

(b) Approved source shall mean the source of water from a spring, artesian well, drilled well, municipal water supply, or any other source which has been evaluated and found to be of satisfactory sanitary quality as determined by the State.

(c) Artesian well water shall mean water that comes from a deep well where water is forced up by underground pressure.

(d) Bottled water shall mean any product, including natural spring or well water taken from municipal or private utility systems or other water, distilled water, deionized water,

or any of the foregoing to which chemicals may be added, which are put into sealed bottles, packages or other containers, to be sold for domestic consumption or culinary use, involving a likelihood of such water being ingested by human beings.

(e) Bottled and Bulk Water Standards shall mean this subpart.

(f) Bulk water shall mean water intended for potable uses which is transported by tank truck.

(g) Commissioner shall mean the Commissioner of Health of the State of New York.

(h) Department shall mean the New York State Department of Health.

(i) Food and Drugs 21 CFR shall mean the Code of Federal Regulations, Title 21, Food and Drugs, as published in the Federal Register, Volume 42, Page 14355, March 15, 1977, as amended by Volume 44, Page 12175, March 6, 1979 and found in 21 CFR, Part 129 - Processing and Bottling of bottled Drinking Water, Pages 137 through 141, revised as of April 1, 1988. A copy is available for public inspection at the offices of the Records Access Officer of the Department of Health, Empire State Plaza, Corning Tower, Albany, NY 12237.

(j) Maximum contaminant level (MCL) shall mean the maximum permissible level of a physical, chemical, radiological or microbiological substance in water.

(k) Multi-use containers shall mean those containers which are intended by the bottler for more than one use.

(l) Nontoxic materials shall mean materials, used in transporting, storing and packaging of bottled or bulk water, which are free of substances which may render the water harmful to health or which may adversely affect the flavor, color, odor, or microbiological or chemical quality of the finished product.

(m) Person shall mean an individual, corporation, company, association, partnership, State agency, municipality, county or Federal agency.

(n) Person in charge shall mean the designated employee or employees who are appointed and in responsible charge of the bottling facility and who are present at all time during the bottling operation.

(o) Principal organic contaminant (POC) shall mean any organic chemical compound belonging to the following classes, except for trichloromethane (chloroform), dibromochloromethane, bromodichloromethane, tribromomethane (bromoform) and any other organic chemical contaminant with a specific MCL listed in section 5-6.11 of this Subpart:

(1) Halogenated Alkane.

(2) Halogenated Ether.

(3) Halobenzenes and Substituted Halobenzenes.

(4) Benzene and Alkyl- or Nitrogen-Substituted Benzenes.

(5) Substituted, Unsaturated Hydrocarbons.

(6) Halogenated Non-aromatic Cyclic Hydrocarbons.

(p) Production line shall mean an assemblage of water bottling equipment which share product water contact surfaces and may be used to fill one or more container types/sizes or product types.

(q) Recommended Standards for Water Works shall mean the New York State Health Department publication, 1987, published by Health Research, Inc., P.O. Box 7126, Albany, NY 12224. A copy is available for public inspection at the offices of the Records Access Officer of the Department of Health, Empire State Plaza, Corning Tower, Albany, NY 12237.

(r) Rural Water Supply shall mean the New York State Department of Health publication by that name as copyrighted in 1966 and reprinted in 1988. A copy is available for public inspection at the offices of the Records Access Officer of the Department of Health, Empire State Plaza, Corning Tower, Albany, NY 12237

(s) Spring water shall mean water derived from an underground formation from which water flows naturally to the surface of the earth.

(t) State shall mean the State Commissioner of Health or his designated representative.

(u) Total trihalomethane (TTHM) shall mean the sum of the concentration of trichloromethane (chloroform), dibromochlormethane, bromodichloromethane and tribromomethane (bromoform).

(v) Unspecified organic contaminant (UOC) shall mean any organic chemical compound not otherwise specified in this Subpart.

(w) Violation shall mean the failure to comply with or conform to the provisions of this subpart.

(x) Well water shall mean water that is taken from below the ground through piping or similar installed device using external force or vacuum.

5-6.4 Sources of water. All sources of water must be approved before use.

(a) The sources of all bulk or bottled drinking water located in New York State must be approved by the State. Sources of all bulk or bottled drinking water located outside New York State must be approved by the agency having jurisdiction.

(b) Sources shall, at a minimum, meet the following requirements:

(1) All sources shall be developed in conformity with up-to-date sanitary engineering practices as set forth in Rural Water Supply and Recommended Standards for Water Works.

(2) All sources shall be located, developed and protected so they are not subject to natural or artificial contamination.

(c) All spring sources shall, at a minimum, meet the following requirements:

(1) A watertight wall shall completely surround the spring, not less than 12 inches above the highest point of ground and extend down through the overburden to the water-bearing stratum. On rock, such walls shall be keyed and sealed with cement grout to the rock. The top of the wall shall be level to accommodate a cover.

(2) A tight-fitting, locked cover shall be installed on the top of the encircling wall. The cover shall be constructed to provide reliable protection against contamination by animals or humans.

(3) Where the spring is protected by a spring house, the building shall be verminproof and shall be kept locked.

(4) A ditch or berm shall be constructed and routinely maintained to divert surface drainage away from the spring.

(5) Spring water shall be collected only at the natural orifice of the spring or through a borehole that is adjacent to the natural orifice. Spring water collected with the assistance of external force or through a bore hole or through a spring head that is otherwise altered to protect the water source shall retain all the physical properties of and be of the same composition and quality as the water that flows naturally to the surface of the earth.

(d) All drilled wells shall, at a minimum, meet the following requirements:

(1) A watertight casing shall be installed to the depth necessary to prevent surface contamination and to seal contamination of undesirable strata. The casing shall be sealed by filling the annular opening between the casing and the earth with cement or cement-sand grout or other approved sealant, at least 1 1/2 inches thick. This seal shall extend from ground surface to a point not less than six inches below groundwater level.

(2) A permanent casing shall be installed to at least 12 inches above the pump house floor or concrete apron surface and at least 18 inches above final ground surface.

(3) Wells shall be located on sites not subjected to flooding or be provided with an earth berm surrounding the casing and terminating at an elevation at least two feet above the highest known flood elevation or have other suitable protection as determined by the State.

(4) Wells shall be equipped with an approved pitless adaptor unit installed at the joint where the discharge pipe passes through the well casing.

5-6.5 Required Treatment. All bottled water facilities packaging water for distribution in New York State must provide satisfactory treatment of each water supply source used.

(a) Minimum treatment of each water supply source used shall be disinfection by chlorination, ozonation, ultraviolet radiation or other disinfection methods as protective of the public health as the above.

(b) The commissioner may, when requested in writing, grant a waiver which is renewable annually, to the disinfection requirement for groundwater sources, if:

(1) The record of the bacteriological characteristics for each groundwater source demonstrates conformance to the maximum contaminant levels for microbiological contaminants in section 5-6.11 of this Subpart, for the 12 months immediately preceding the date of application for waiver; such record shall be established under procedures provided by the commissioner.

(2) A laboratory as described in section 5-6.13 of this Subpart is used by the bottling facility to provide monitoring of source and finished product water quality.

(c) Where treatment is provided, all equipment must meet, as a minimum, the standards outlined in Recommended Standards for Water Works.

5-6.6 Bottling plant facilities. Bottling plants must be constructed to facilitate cleanliness and be maintained to maximize sanitation and public health protection.

(a) Buildings and rooms shall be of sufficient size to allow for the proper installation of equipment and to allow for movement of personnel during operation.

(b) The bottle filling operations shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors or other appropriate barriers to isolate these areas and provide protection against incidental contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(c) Plant buildings shall be vermin proof.

(d) Walls and ceilings shall be smooth, light color, washable and kept in good repair. Overhead structures, fixtures, ducts, and pipes shall not be suspended over working areas so that drip or condensate may contaminate products or product contact surfaces.

(e) Floors shall be smooth, nonabsorbent and vermin proof. Floors are to be graded to adequate drains equipped with traps and grills.

(f) Doors and windows to outside areas shall be adequately screened and/or otherwise protected against entry of vermin, airborne contamination, and particulates.

(g) All rooms are to be provided with sufficient ventilation to keep them free of excessive heat, steam, condensation, vapors, odors, and fumes.

(h) Lighting, either natural or artificial, shall be provided in all rooms where bottled or packaged waters are produced. An intensity of not less than 50 foot-candles shall be

provided in inspection areas; 30 foot-candles in work spaces, and five foot-candles in storage areas. Light bulbs, fixtures, skylights or other glass suspended over exposed production areas shall be of the safety type or otherwise protected from breakage to prevent finished product contamination.

(i) Washrooms shall be convenient, separate, and apart from any room or rooms where bottled or packaged water is processed and from areas where bottles and packages are sanitized. Toilets, urinals and wash basins shall be provided, as appropriate, for the number of employees. Washrooms shall be equipped with self-closing doors and fitted with windows or separate ventilation to the outside. Signs shall be posted directing employees to wash their hands after using the toilet.

(j) Clean, dry storage facilities shall be provided for finished product containers and packaging materials.

(k) Dressing rooms shall be provided for changing and hanging street apparel and shall be apart and separate from work areas.

(l) Wastewater disposal shall be provided and have discharge to a municipal wastewater system or a State approved individual wastewater disposal system.

5-6.7 Production, equipment, and packaging. All bottled water production, including transporting, packaging, and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for chemical contamination, undesirable bacterial or other microbiological growth, toxic formation, deterioration, or contamination of the finished product.

(a) Bottles must be mechanically filled and closed.

(b) Fillers, piping, pumps and other process equipment used in the production of bottled water products may not be used for the production of milk and/or dairy products. Other beverage production that may impart deleterious substances to bottled water produced in the same equipment or cause microbiological contamination of the bottled water, may also be prohibited when the contamination is confirmed by two documented cases.

(c) All equipment shall be of sanitary design and shall be constructed of nontoxic, nonabsorbent material which will not impart flavor, color or odor to the bottled water. All equipment shall be installed and maintained to facilitate the cleaning of equipment and of all adjacent spaces. All material used in the design, construction and repair of the water transmission and/or production piping in a bottled or bulk water facility must be lead free. For this Subpart, lead free shall mean solder or flux which contains no more than 0.2 percent lead and pipes, pipefittings and any appurtenances which contain no more than eight percent lead.

(d) Storage tanks used for bottled water production shall be:

(1) Tightly closed to exclude all foreign matter and vented through inverted air filters.

(2) Without connections to sources of water not approved in writing, by the State or the governmental regulatory agency having jurisdiction over facilities located outside the State.

(3) Protected from cross-connection and equipped with backflow prevention devices approved by the State or the governmental regulatory agency having jurisdiction over facilities located outside the State.

(4) Equipped with linings or coatings conforming to the listing of acceptable linings for process and potable water tanks from the State or the governmental regulatory agency having jurisdiction over facilities located outside the State.

(5) Used only for water and not for storage of any other food product or non-food substance.

(e) There shall be no cross-connections between finished product water lines and any other water pipelines.

(f) Hoppers shall be provided with covers.

(g) Fillers shall have the inlet so designed as to prevent the entrance of condensation. Filling valves shall be equipped with a condensation-diverting apron.

(h) Containers and packaging shall, at a minimum, meet the following requirements:

(1) Packaging processes and materials shall not transmit contaminants or objectionable, toxic or deleterious substances to the bottled water.

(2) Containers and closures for bottled water shall be in compliance with those requirements contained in Food and Drugs 21 CFR.

(3) Only sanitary, nontoxic lubricants shall be used on container contact surfaces.

(4) Bottles shall be provided with a tamper-evident seal or cap.

(5) Screw, snap and crown caps shall be new.

(6) Screw, snap and crown caps must be sanitized unless protected and received clean and kept free from bacterial contamination.

(7) When sanitized bottles cannot be filled immediately, they shall be closed or covered immediately when removed from packages. When they are to be filled, such closed bottles shall be opened, resanitized, filled and closed immediately in one continuous operation.

(8) All cleaned bottles shall be protected from dust, dirt, insects, debris and other forms of contamination.

(9) Each container of bottled drinking water shall be identified by a clear and conspicuous production code indicating, in English, the day, month and year of

production. The production code shall identify a particular batch or segment of a continuous production run. The plant shall record and maintain information as to the kind of product, volume produced, date produced, production code used and the distribution of the finished product to wholesale and retail outlets to which the plant directly supplies product.

(10) Multi-use containers shall have the production date code affixed to the primary container. Cap coding is not acceptable unless the dispenser system retains the cap with the multi-use container, after opening.

(i) The plant shall have on file a written recall plan which shall detail procedures for recall of any particular batch as identified by the production code.

5-6.8 Sanitation and maintenance. Buildings, fixtures and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of product and product contact surfaces. Detergents, sanitizers and other materials used in cleaning and sanitizing procedures shall be free of chemical or microbiological contamination and shall be safe and effective for their intended use. Only such materials as required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation or used in manufacturing or processing operations, shall be stored in the plant. These materials shall be identified and used only in such manner and conditions that will be safe for their intended use.

(a) Storage tanks shall, at a minimum, meet the following requirements:

(1) Inspected for cleanliness on a monthly basis and kept free of scale, evidence of oxidation and residue.

(2) Cleaned on a monthly basis by sanitizing with one of the following and flushing with finished product water:

(i) chlorine water solution of 200 parts per million (ppm) for a minimum of five minutes;

(ii) spray wet surface with 200 ppm chlorine water solution. This is to be used on surfaces that are not reached by the above soaking treatment;

(iii) bactericides, such as organic chlorine compounds and bactericidal agents containing iodine or bromine; and

(iv) 0.1 ppm ozone water solution for or not less than 10 minutes contact time.

(b) Product water pipelines shall, at a minimum, meet the following requirements:

(1) Kept free of scale, evidence of oxidation and residue.

(2) Cleaned on a daily basis by sanitizing with one of the following:

(i) water containing at least 200 ppm of chlorine for a minimum of five minutes, followed by flushing with finished product water; or

(ii) the continuous re-circulation of at least 0.1 ppm ozonated water.

(c) Product equipment shall, at a minimum, meet the following requirements:

(1) Cappers shall be kept free of residue and sanitized on a daily basis.

(2) Hoppers shall be kept covered, free of residue and sanitized on a daily basis.

(3) Ozone mixing tanks and equipment, soft water tanks and other associated equipment shall be inspected on a monthly basis, disassembled if necessary, cleaned and sanitized as needed.

(4) Bottle washing equipment shall be kept free of paper residue and substances which may interfere with proper operation of jets. Internal sprays shall be checked daily to assure proper timing and adequate washing of bottles.

(5) Fillers shall be kept free from scale, evidence of oxidation and residue and shall be sanitized on a daily basis. Filling and capping operations shall be so conducted as to prevent contamination of water being bottled. The filler reservoir shall be kept covered at all times.

(d) Personnel shall, at a minimum, meet the following requirements:

(1) Employees shall wear clean outer garments and caps while bottling; packaging water or sanitizing bottles and packages.

(2) Expectorating is prohibited, except into receptacles for wastewater or sewage.

(3) Before starting work and immediately after visiting a toilet, smoking, eating, drinking or any other activity that soils the hands, every person shall wash his hands and forearms with soap and warm water and thoroughly rinse them in clean water.

(4) No person affected by disease in a communicable form or while a carrier of such disease or while affected with boils, sores, infected wounds or other abnormal sources of microbiological contamination, shall knowingly be permitted to work in a bottled water plant in any capacity, if there is a reasonable possibility of finished product water becoming contaminated by such person or of disease being transmitted by such persons or other individuals.

(5) Tobacco shall not be used in any product-processing room.

(6) Eating and drinking is prohibited in product-processing rooms.

5-6.9 Sanitizing bottles. The bottles shall be properly sanitized before use by using approved methods and approved sanitizing agents.

(a) Before filling, all multi-use containers shall be thoroughly washed in an effective cleansing agent and water solution, having a temperature not less than 120 degrees Fahrenheit, followed by application of a bactericidal solution and the inside rinsed with finished product water to remove traces of sanitizing agents.

(b) The bactericidal procedure for the inside of bottles, as a minimum, shall be one of the following:

(1) Sanitize with 100 ppm chlorine water solution at 75 degrees Fahrenheit for not less than 30 seconds.

(2) Sanitize with a 2-1/2 percent caustic solution at a minimum temperature of 120 degrees Fahrenheit followed by a rinse containing not less than 10 ppm free chlorine. Note: When caustic is discharged by high-velocity jets, this procedure shall be considered to satisfy both cleaning and bactericidal requirements.

(3) Sanitize with water at an inside bottle temperature of not less than 170 degrees Fahrenheit for not less than 15 seconds.

(4) Sanitize by exposing all surfaces to a three percent caustic solution at a minimum temperature of 120 degrees Fahrenheit for five minutes -- by automatic bottle washers using high-velocity, hydro-type jets or by soaker washers -- followed by a rinse containing not less than 10 ppm free chlorine.

(5) Other methods equally protective of public health as the above, when approved by the State, may be used.

(c) Single-use bottles or containers, which are free of all bacteria, dust or other contamination, need not comply with the above sanitizing requirement before filling.

5-6.10 Maximum contaminant levels.

(a) The MCLs listed in section 5-6.11 of this Subpart shall not be exceeded.

(b) The owner or operator of the bottled or bulk water facility is responsible for completion of the sampling and analytical requirements set forth in this Subpart. At the discretion of the State, analyses performed by the State may be used for monitoring purposes.

(c) If the result of a monitoring sample analysis exceeds the MCL for a physical contaminant, except for turbidity or an inorganic chemical contaminant, except for nitrate, the owner or operator of the bottled or bulk facility shall collect and analyze three more samples from the same production run, when feasible, but no later than 24 hours of learning of a potential violation. An MCL violation occurs when the average, rounded to the same number of significant figures as the MCL in question, of the four results exceeds the MCL. For nitrate, the owner or operator of the bottled or bulk water facility shall collect and analyze one more sample from the same production run, when feasible, but no later than 24 hours of learning of a potential violation. An MCL violation occurs when the average of the two results exceeds the MCL.

(d) If the result of a monitoring sample analysis exceeds the MCL for the general organic chemical contaminants, the owner or operator of the bottled or bulk facility shall collect and analyze one to three more samples from the same production run, when feasible, but no later than 24 hours of learning of a potential violation. An MCL violation occurs when at least one of the confirming samples is positive and the average of the initial sample and all the confirming samples exceeds the MCL.

(e) The commissioner may exempt bottled water from the chemical and radiological MCLs based on justification, submitted by the owner or operator of the bottled water facility, that granting of the exemption would not result in public health hazard. If an exemption is granted, an appropriate label, approved by the commissioner, shall be conspicuously placed on all bottles and/or containers of such exempted bottled water produced, distributed and/or sold within New York State in accordance with subdivision 5-6.12(b) of this Subpart.

(f) All analyses for general organic chemicals must be performed in accordance with the U.S. Environmental Protection Agency (EPA) Methods 502.1, 503.1, 524.1, 524.2, or 502.2, at a detection limit not to exceed 0.0005 milligrams per liter. If the State has reason to believe that an MCL has been violated, the potential exists for an MCL violation or the contaminant may present a risk to public health, principal organic contaminant analyses shall also include EPA Methods 504, 625, 604, 605, 608, 609, 611, or 612, as appropriate. EPA Methods 502.1, 503.1, 524.1, 524.2, 502.2 and 504 mean, respectively, "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography;" "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography;" "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry"; "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry," "Volatile Organic Compounds in Water by Purge and Trap Capillary Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series"; and "Measurement of 1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-chloropropane (DBCP) in Drinking Water by Microextraction and Gas Chromatography." These methods are contained in "Methods for Determination of Organic Compounds in Finished Drinking Water and Raw Source Water"; September 1986. Copies of this publication can be obtained from Environmental Monitoring and Support Laboratory, EPA, Cincinnati, Ohio 45268, and a copy is available for inspection and copying at the offices of the Records Access Officer of the Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237. EPA Methods 604, 605, 608, 609, 611, 612, and 625 mean respectively "Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater; Methods 604 - Phenols; Method 605 - Benzidines; Method 608 - Organochlorine Pesticides and PCBs; Method 609 - Nitroaromatics and Isophorone; Method 611 - Haloethers; Method 612 - Chlorinated Hydrocarbons; and Method 625 - Base/Neutrals and Acids." These methods are contained in 40 CFR Part 136 as published in the Federal Register, Volume 49, page 43250, No. 209, Friday, October 26, 1984. Copies of this publication are available from U.S. Environmental Protection Agency, Public Information Reference Unit, 401 M Street, S.W., Washington, D.C. 20460 and a copy is available for inspection and copying at the offices of the Records Access Officer of the Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237.

5-6.11 Tables

TABLE 1 - BOTTLED WATER SAMPLING REQUIREMENTS

Contaminant	Maximum Contaminant Levels	Frequency of Samples	Number of Samples	
			Source Water	Finished Product [1]
Microbiological:		See Table 1A		
- Heterotrophic	*2			
- Microorganisms				
- Total Coliform	Less than 1 organism per 100 ml[3]			
Radiological:				
- Gross Alpha Particle Activity (including Radium 226 but excluding Radon and Uranium	15 picocuries per liter	Yearly	1[6]	1[6]
- Combined Radium 226 and Radium 228	5 picocuries per liter	Yearly	1[6]	1[6]
- Beta particle and photon activity from manmade radionuclides	4 millireams per year	Yearly	1[6]	1[6]
Physical:		Yearly	1	1
- Turbidity	5 Units			
- Color	15 Units			
- Odor	Threshold Odor No. 3			

TABLE 1 - (CONT'D)

Contaminant	Maximum Contaminant Levels in Milligrams/Liter	Frequency of Samples	Number of Samples	
			Source Water	Finished Product [1]
Inorganic Chemical:		Yearly[4]	1[5 6]	1[5 6]
Arsenic (As)	0.05			
Barium (Ba)	1.0			
Cadmium (Cd)	0.01			
Chloride (Cl)	250.0			
Chromium (Cr)	0.05			
Copper (Cu)	1.0			
Fluoride (F)	2.2			
Iron (Fe)	0.3			
Lead (Pb)	0.05			
Manganese (Mn)	0.3			
Mercury (Hg)	0.002			
Nitrate (N)	10.0			
Selenium (Se)	0.01			
Silver (Ag)	0.05			
Sulfate (SO4)	250.0			
Zinc (Zn)	5.0			
Alkalinity	[*2]			
Corrosivity	[*2]			
Hardness	[*2]			
pH	[*2]			
Sodium (Na)	[*2]			
Total Dissolved Solids	[*2]			

TABLE 1 - (CONT'D)

Contaminant	Maximum Contaminant Levels in Milligrams Per Liter	Frequency of Samples	Number of Samples: Source Water	Number of Samples: Finished Product [1]
	Organic Chemical:			
Pesticides/Herbicides		Yearly[4]	1[5 6]	1[5 6]
Endrin	0.0002			
Lindane	0.004			
Methoxychlor	0.050			
Toxaphene	0.005			
2,4-D	0.050			
2,4,5-TP (Silvex)	0.01			
Trihalomethanes		Yearly		1[5 6]
Total Trihalomethane (TTHM)	0.10			
General Organic Chemicals				
Principal Organic Contaminant (See Table 1B for listing of monitored contaminants.)	0.005	Yearly[4]	1[5 6]	1[5 6]
Unspecified Organic Contaminants	0.050	None specified		
Total of all POCs and UOCs	0.10	None specified		
Vinyl Chloride	0.002	Yearly[4]	1[5 6]	1[5 6]

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TABLE 1 (CONT'D)

[1] Samples shall be collected and analyzed for each production line and product type. If more than one container size is bottled at the facility, a plan to rotate sampling of container sizes shall be submitted to and approved by the Department.

[2] No maximum contaminant level established.

[3] No positive total coliform result.

[4] All monitoring samples shall be collected and analyzed in the first quarter of the calendar year, unless otherwise specified by the State.

[5] Every third year, beginning in 1992, or in the first full calendar year following certification, four quarterly monitoring samples shall be collected and analyzed.

[6] The owner or operator of a bottled water facility shall require the approved laboratory performing the analyses to send a copy of the laboratory report directly to the Department. The owner or operator of a bottled water facility shall submit with the next monthly monitoring report following receipt of the laboratory report a letter to the Department, certifying that the aforementioned laboratory report accurately represents the quality of the described bottled water product and that the bottled water product complies with the organic, inorganic, radiological and other water quality standards in this Subpart.

5-6.11 Tables

TABLE 1A - MICROBIOLOGICAL SAMPLING FREQUENCY

Total Gallons Produced Per Month	Minimum Number of Samples					
	Uncarbonated Bottled Water		Carbonated Bottled Water		Bulk Water	
	Finished Product Per Week	Source Water Per Month	Finished Product Per Month	Source Water Per Month	Finished Product Per Month	Source Water Per Month
1 to 39,999	1	1	1	1	1	1
40,000 to 79,999	2	2	1	1	1	1
80,000 to 299,999	3	2	1	1	1	1
300,000 to 699,999	4	3	1	1	1	1
700,000 and more	5	3	1	1	1	1

TABLE 1B - PRINCIPAL ORGANIC CHEMICALS

benzene	1,1-dichloropropene
bromobenzene	cis-1,3-dichloropropene
bromochloromethane	trans-1,3,-dichloropropene
bromomethane	ethylbenzene
n-butylbenzene	hexachlorobutadiene
sec-butylbenzene	isopropylbenzene
tert-butylbenzene	p-isopropyltoluene
carbon tetrochloride	methylene chloride
chlorobenzene	n-propylbenzene
chloroethane	styrene
chloromethane	1,1,1,2-tetrachloroethane
2-chlorotoluene	1,1,2,2,-tetrachloroethane
4-chlorotoluene	tetrachloroethene
dibromomethane	toluene
1,2-dichlorobenzene	1,2,3-trichlorobenzene
1,3-dichlorobenzene	1,2,4-trichlorobenzene
1,4-dichlorobenzene	1,1,1-trichloroethane
dichlorodifluoromethane	1,1,2-trichloroethane
1,1-dichloroethane	trichloroethene
1,2-dichloroethane	trichlorofluoromethane
1,1-dichloroethene	1,2,3-trichloropropane
cis-1,2-dichloroethene	1,2,4-trimethylbenzene
trans-1,2-dichloroethene	1,3,5-trimethylbenzene
1,2-dichloropropane	m-xylene
1,3-dichloropropane	o-xylene
2,2-dichloropropane	o-xylene

5-6.12 Labeling. Each bottle or container shall bear a label, to be affixed to each bottle or container before it leaves the plant. Wording shall be printed in English, in legible type which shall be in contrast by typography, layout or color, with other printed matter on the level, cap, or container.

(a) Each label shall show:

(1) The type of source water:

(i) For water coming from springs: "Spring Water".

(ii) For artesian or pumped water taken from the ground, from drilled wells or approved dug wells: "Well Water".

(iii) For a municipal water supply source, the name of the municipal supply, such as "New York City Pubic Water Supply", "Buffalo City Public Water Supply", etc.

(iv) For bottled water identified on the label as being distilled, the type of source water does not need to be shown.

(2) Address and location of the bottling facility or corporate offices.

(3) Net contents and/or capacity of the container.

(4) The assigned New York State Health Department certificate number. Abbreviations are limited to "NYSHD Cert. #000."

(5) Where sodium content information is provided, a statement of the number of milligrams of sodium in a specified serving and the net quantity (measure) of each serving shall be placed on the label.

(b) In all situations where the commissioner has exempted a bottled water from the inorganic chemical and/or radiological maximum contaminant levels, an appropriate label, approved by the commissioner, shall be conspicuously placed on all bottles or containers of such exempted water manufactured, distributed or sold at retail within the State of New York. The label shall contain the statement:

"This water contains levels of minerals* in excess of standards for drinking water established by the New York State Commissioner of Health and, therefore, should not be used as a principal or sole source of drinking water."

*The specific minerals in excess of standards may be placed anywhere on the bottle.

5-6.13 Sampling, methods and record keeping

(a) Bottled water shall be sampled at the frequency and analyzed for the water quality parameters outlined in section 5-6.11 of this Subpart.

(b) Samples for any water quality parameter not specified in section 5-6.11 of this Subpart shall be collected and analyzed as may be required the State.

(c) Sampling methods and analyses shall, at a minimum, meet the following requirements:

(1) Source water samples shall be taken from each approved source.

(2) Finished product water samples shall be taken from a batch or segment of a continuous production run for each type of bottled water produced during a day's production. The representative sample shall consist of a primary container of the finished product.

(3) All required finished product water quality analyses must be performed by an approved laboratory.

(4) All required source water quality analyses must be performed by an approved laboratory.

(5) Analysis shall be conducted by the analytical requirements set forth in Standard Methods for the Examination of Water and Wastewater, current edition, or alternate methods approved by the department's Environmental Laboratory Approval Program.

(d) Container sampling for each container size shall, at a minimum, meet the following requirements:

(1) Containers and closures shall be inspected to verify that they are free from contamination.

(2) At least once every three months, a total coliform swab and/or rinse count should be made from at least four containers and closures selected just before filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these total coliform tests shall be in conformance with those recognized by the State. Tests shall be performed by qualified plant personnel or an approved laboratory.

(e) Record retention and reporting shall, at a minimum, meet the following requirements:

(1) Records shall be kept of all inspections, cleaning and sanitizing operations and bottling production. Records of all microbiological and chemical testing must also be maintained by owners and operators of bottled and bulk water facilities and shall be available to the State for the most recent five year period for microbiological analyses and ten years for chemical analyses.

(2) Monthly operating reports for bottlers operating in New York State shall be submitted to the State. Reports shall include the total monthly production including specific production figures for finished product intended for distribution and sale in New York State and all physical, chemical, radiological and microbiological analytical results for that month; the treatment processes and chemicals used; sources of

water; and other pertinent data. Form GEN 221, Report on Bottled Water Operation or a form containing equivalent information shall be used for this purpose. Failure to submit these reports shall be cause for suspension and/or revocation of the Certificate of Approval.

(3) Out-of-State bottlers shall submit their month operating reports no later than the 10th of the month following the month of the reporting period. The annual inspection report performed by the government agency having jurisdiction shall be submitted each year. The monthly operating reports and annual inspection report are to be sent directly to:

New York State Department of Health
Bureau of Public Water Supply Protection
Flanigan Square
547 River Street
Troy, NY 12180-2216

5-6.14 Notification. Any person who owns or operates a bottled or bulk water facility must notify the State by telephone, facsimile (FAX) copy or other means when feasible, but no later than 24 hours of learning of the existence or potential existence of a violation of Section 5-6.11 of this Subpart.

5-6.15 Bulk water. All bulk water sources and facilities must be approved and maintained for sanitary quality at all times.

(a) All sources of water for bulk water shipment must be approved by the New York State Health Department and must meet the source requirements outlined in Section 5-6.4 of this Subpart and the treatment requirements outlined in section 5-6.5 of this Subpart.

(b) All water storage facilities must be maintained clean and sanitary at all times and must meet the requirements outlined in section 5-6.8 of this Subpart.

(c) Tank trucks, loading and unloading facilities and other equipment used to transport bulk water shall be maintained clean and sanitary at all times. Tanks previously used to transport toxic materials, petroleum products or other deleterious substances shall not be used to haul drinking water.

(d) Bulk transport and transfer procedures shall, at a minimum, meet the following requirements:

(1) Before filling, the tank interior shall be cleaned, flushed with potable water, sanitized with water containing not less than 100 ppm chlorine for a contact period of not less than 20 minutes and rinsed with potable water.

(2) Tanks also used for the transport of dairy products must have the interior of the tank inspected with an ultraviolet lamp by the hauler each time water is to be transported. Tanks shall be rejected for use when odors or contaminants are found. The dome cover shall be closed immediately after inspection.

(3) All hoses, connections and fittings shall be sanitized with a concentrated solution of chlorine, 3 ounces of 5 1/4 percent household bleach to 2 gallons of water, by brushing solution on all exposed parts.

(4) The cover shall not be opened after sanitizing.

(5) Notwithstanding the above, the frequency of tank sanitization may be reduced, on approval by the State, based on satisfactory demonstration of sanitary handling for bulk tanks used solely for potable water transport.

(6) Tank trucks or tank trailers may be filled through the fitting on the inner dome cover when the tail pipe cannot be used.

(7) Water quality in the tank, after 20-30 gallons have been delivered into the tank, shall be checked as follows:

(i) stop filling;

(ii) have discharge valve opened;

(iii) inspect water as it discharges. If water has unpleasant odor and/or looks dirty, it shall be rejected for use; and

(iv) when these checks show satisfactory water quality, proceed to fill the tank.

(8) The dome cover shall be closed and sealed after filing to volume desired.

(9) The tank discharge valve cover shall be closed and sealed after filling.

(10) When a fill connection is used, it shall be constructed in a manner to prevent contamination and shall be capped at all times when not in use.

(e) The number and type of sample, frequency and points of sampling shall be in accordance with requirements outlined in section 5-6.11 of this Subpart or a program approved or directed by the State.

(f) Analysis of the samples must be performed for the plant by an approved laboratory as outlined in section 5-6.13 of this Subpart.

(g) Records shall, at a minimum:

(1) Include the number of gallons delivered daily, cleansing and sanitizing methods used for tank truck and tank trailer interiors, risers, connections, hoses, etc.;

(2) include date, time and location of delivery, concentration of solution, time of contact when applicable, and water quality analysis results as evidence of compliance with the sampling requirements of this Subpart; and

(3) be submitted on a monthly basis to the State.

5-6.16 Certification procedures. All bottled or bulk water products sold or distributed in New York State must be certified. The following procedures must be met to apply for certification:

(a) Any person applying for bottled water certification shall, at a minimum, meet the requirements listed below:

(1) Complete and submit a signed application form, GEN. 222 Application for Certification of Approval for Distribution of Bottled or Bulk Water.

(2) Submit a statement from the appropriate regulatory agency of the state or country having jurisdiction over the bottling operation, indicating that the facility has been approved to bottle or package water for human consumption. This approval may be a copy of a certificate, license, permit or a letter of approval from the agency. A copy of the laws and regulations on bottled water processing from the regulatory agency having jurisdiction must also be submitted. When another state or country has no program for inspection and approval of bulk or bottled water facilities, the commissioner may make a determination based on an inspection and evaluation by an independent individual or organization knowledgeable in bulk or bottled water handing practices.

(3) Submit an engineering report, plans and specifications for the proposal prepared by a registered Professional Engineer licensed to practice in New York State or in the state which the facility is located. This submittal must include, but not be limited to, the development of the source, methods used in the bottling operation, the water treatment used and laboratory control of water quality provided and a flow diagram from source through the bottling operation. The report submitted with the application must show compliance with the requirements of this Subpart.

(4) Submit two caps and two labels for each container size of the bottled water product that is to be certified.

(5) Submit complete inorganic chemical, organic chemical, microbiological and radiological analyses for contaminants listed in section 5-6.11 to this Subpart for each source and each finished bottled water product type to be distributed in New York State. Results of these analyses must be submitted with the application. Additional analyses may be required, if in the judgement of the commissioner they are needed to determine the acceptability of the source or treatment provided. All analyses must be performed by an approved laboratory and in accordance with the sampling methods as outlined in section 5-6.13 of this Subpart. All analyses must have been performed within the last six months from the date of the application for or certification, except for the microbiological analyses which must have been performed within thirty days from the date of the application for certification.

(6) Submit a list of names, addresses and telephone numbers of those who are now or are expected to be distributing the product in New York State.

(7) Submit a recall plan in accordance with the requirements as outlined in section 5-6.7 of this Subpart.

(b) Any person applying for a maximum contaminant level exemption of a bottled water product shall, at a minimum, meet the requirements listed below:

(1) An exemption request must be submitted with the above certification data for each chemical or radiological contaminant that exceeds the MCL. No exemption will be given for microbiological or organic chemical MCLs.

(2) The request must include documentation that the contaminant exceeding the MCL will not constitute an unreasonable health risk. The documentation must include:

(i) the identification of the contaminant or contaminants exceeding the MCL;

(ii) the concentration level in milligrams per liter of the contaminant, including the maximum, minimum and average value found in the product;

(iii) the target consumer group;

(iv) the consumption pattern in milliliters per day of the consumers based on estimated or actual market surveys; and

(v) the health significance of the higher contaminant concentration level.

(c) Any person applying for bulk water certification shall, at a minimum, meet the requirements listed below:

(1) Complete and submit a signed application form, GEN 222 Application for Certification of Approval for Distribution of Bottled or Bulk Water.

(2) Submit a statement from the appropriate regulatory agency of the state having jurisdiction over the bulk water operation indicating that an inspection of the water source, transporting vehicles and sanitation procedures has been made and is in conformance with the appropriate minimum standards as outlined in this Subpart. When another state has no program for inspection and approval of bulk water operators, the commissioner may make a determination based on an inspection and evaluation by an independent individual or organization knowledgeable in bulk water handing practices.

(3) Submit a report that includes the procedures used in the sanitizing of the tank interior, the name and location of the source water, source treatment, other uses of the tank truck, frequency and type of water quality analyses performed, quantities and frequencies of shipments, primary use of potable water shipped and loading and unloading procedures.

(4) Submit complete inorganic chemical, organic chemical, microbiological and radiological analyses for contaminants as listed in section 5-6.11 of this Subpart for each source to be used. Results of these analyses must be submitted with the application. Additional analyses may be required if, in the judgement of the commissioner, they are needed to determine the acceptability of the source or treatment provided. All analyses must be performed in accordance with the sampling methods as outlined in section 5-6.13 of this Subpart. All analyses must have been performed within the last six months from the date of the application for certification, except for the microbiological analyses which must have been performed within thirty days from the date of the application for or certification.

(d) The following conditions must be met to maintain certification approval:

(1) Each year, a statement must be submitted from the appropriate regulatory agency of the state or country having jurisdiction over the bottling facility indicating that the facility has been inspected and approved to bottled or package water for human consumption.

(2) Each month, a form GEN 221 Report on Bottled Water Operation, must be completed and submitted no later than the 10th of the month following the month of the reporting period. The microbiological sample results on source and finished products must conform to the requirements of sections 5-6.10, 5-6.11 and 5-6.13 of this Subpart. Results of each analysis must be entered on the GEN. 221 opposite the date the sample was collected. The quantity of water shipped for distribution in New York State must be entered on the GEN. 221 in the daily product column opposite the date of actual shipment.

(3) The required organic chemical, inorganic chemical and radiological analyses on the source and finished water product, must be completed for the calendar year as required in section 5-6.11 of this Subpart.

(4) Any interruption or change in the operation or treatment, or a change of source shall be reported immediately to the State. Submission of plans or an engineering report may be required.

(5) All exemptions requests must be submitted by July 1st for the calendar year. The required annual water quality monitoring data will be reviewed along with any other available data. Besides the submission of data for maintaining approval, the data as outlined in subdivision (b) of this section, must also be submitted.

5-6.17 Violations. Violations of this Subpart may subject the owner or operator of the bottled or bulk water facility to civil penalties of up to $2,000 per violation, revocation of their certificate of approval to distribute bottled or bulk water within New York State and/or a recall of all product on the market in New York State.

5-6.18 Separability. If any provision of this Part are held invalid, such invalidity shall not affect other portions which can be given effect without the invalid provisions.

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