



NEW JERSEY STATE
DEPARTMENT OF HEALTH & SENIOR SERVICES
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**RULES GOVERNING THE
MANUFACTURE, STORAGE, DISTRIBUTION
AND HANDLING OF BOTTLED WATER
N.J.A.C. 8:21-5.1 et. seq**

**SUBCHAPTER 5.
MANUFACTURING, STORAGE,
DISTRIBUTION, AND
HANDLING OF BOTTLED WATER**

8:21-5.1 Separability

If any provision or application of any provision of this subchapter is held invalid, that invalidity shall not affect other provisions or applications of this subchapter.

8:21-5.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practices.

"Adulteration" means the term "adulteration" as defined in N.J.S.A. 24:5-8.

"Approved" means acceptable to the Department, local health authority, or other appropriate administrative agency based on its determination as to the conformance with applicable standards and good public health practices.

"Approved source" means 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 governmental regulatory agency having primary jurisdiction for that source.

"Aquifer" means a water bearing stratum used as a source of potable water supply.

"Bottled water" means water that falls within the definition established under 21 CFR 165.110(a)(1).

"Bulk water facility" means a place where water intended for potable uses is drawn from an approved source which is transported to a bottling plant by means of tank trucks.

"Certified laboratory" means a laboratory approved by the New Jersey State Department of Environmental Protection in accordance with N.J.A.C. 7:18, Regulations Governing Laboratory Certification and Standards of Performance.

"CFR" means the Code of Federal Regulations.

"Department" means the New Jersey Department of Health and Senior Services.

"Drilled well" means a system whereby water is taken from below the ground through a pipe or piping system or similar installed device utilizing external force or vacuum.

"Expiration date" means the date established by N.J.S.A. 24:12-2 as two years from the date the product was bottled.

"Lot" means a collection of primary containers or units as defined under 21 CFR 165.3.

"Misbranded" means the term "misbranded" as defined in N.J.S.A. 24:5-16 and 17.

"Multi-use containers" means containers intended for use more than one time.

"Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, or packaging of bottled drinking water which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor or bacteriological quality of the water.

"Operations water" means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment clean up and for other sanitary purposes.

"Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, storage, processing, packaging, labeling or handling of bottled water.

"Product contact surfaces" means those surfaces that contact product and those surfaces from which drainage onto product or onto surfaces that contact product ordinarily occurs during the normal course of operations.

"Product water" means processed water used by a plant for bottled drinking water.

"Sanitize" means adequate treatment of surfaces by a process that is effective in destroying the vegetative cell of microorganisms of public health significance and in substantially reducing numbers of other microorganisms.

"Source water" means water from a spring, artesian well, drilled well, community water supply or any other approved source which is used for or in connection with bottled water.

"Spring house" means a structure approved by the Department that is constructed over a spring so as to provide complete protection for the source from all types of external sources of contamination.

"Water hauler" means any person who causes bulk water to be transported for bottling for human consumption or other consumer uses from the source to the bottling plant.

8:21-5.3 Water source protection

(a) The source water supply for bottled water shall be from an approved source which is properly located, protected, and operated and shall be easily accessible, adequate, and of safe, sanitary quality. The water quality and sampling frequency shall be in conformance at all times with the applicable laws and rules and regulations of the Department or other governmental agencies having jurisdiction. Examples of source water supplies which may be used for bottled water upon approval by the Department are as follows:

1. Approved public community water systems;
2. Drilled and driven wells when constructed and protected in accordance with applicable standards set forth in N.J.A.C. 7:10-12, Standards for the Construction of Public Non-community and Non-public Water Systems; and
3. Springs inspected for development as a water source and constructed in accordance with the applicable standards established by the Department of Environmental Protection and set forth in N.J.A.C. 7:10-12.24, Standards for the Construction of Public Non-Community and Non-

Public Water Systems (springs) and shall meet the standards for springs set forth under N.J.A.C. 8:21-5.4.

(b) Source water shall be evaluated according to provisions of N.J.A.C. 7:10-9.4, monitoring requirements and criteria for determination for ground water sources under the direct influence of surface water as defined under N.J.A.C. 7:10-11.4(c)1, 2, and 3. Water sources determined to be under the direct influence of surface water shall comply with the provisions of N.J.A.C. 7:10-9.1 and 9.2.

8:21-5.4 Springs

(a) The spring shall be properly protected from the entry of insects, birds, rodents and other vermin.

(b) Adequate ventilation shall be provided.

(c) Sufficient protection shall be provided at the intake end of the draw pipe to prevent the introduction of stone, gravel, sand and other particulate matter.

(d) The overflow shall be free-flowing and shall be constructed in a manner to prevent flooding of the springhouse and surrounding area.

(e) The minimum distance from a spring to a building sewer line, septic tank, and a distribution box shall be 50 feet. The minimum distance from a spring to a disposal field or seepage pit shall be 100 feet.

(f) Plumbing shall be sized, installed and maintained in accordance with applicable State and local standards. Also, plumbing shall be properly designed and protected from contamination and damage.

(g) Walls and ceilings shall be smooth, easily cleanable, free of cracks and crevices and constructed of materials that are not adversely affected by moisture, algae, or mold.

(h) Proper cleaning and sanitization equipment and facilities shall be available and used whenever a spring is damaged, repaired and/or contaminated.

8:21-5.5 Bottled water labeling requirements

(a) Bottled water shall be labeled and conform with the nomenclature established under 21 CFR 165.110(a) (identity).

(b) Each container of bottled water shall have printed on the container an expiration date of two

years from the date the water was bottled. Bottled water shall no longer be offered for sale, distributed, or given to the public for consumption after the expiration date.

(c) Label claims of medicinal or health-giving properties shall be prohibited. In addition, references to bacteriological purity or laboratory examination which may have been made by a governmental agency shall also be prohibited.

(d) Products which are not in conformance with the above referenced bottled drinking water labeling requirements shall be deemed misbranded as defined at N.J.S.A. 24:5-16 and 17.

8:21-5.6 Facilities for the storage, distribution, handling, and bottling of bottled water

(a) The grounds surrounding the plant shall be kept in a condition that will not cause the bottled water to be contaminated and/or adulterated.

1. Equipment storage, litter, waste, and excessive weeds or grass within the immediate vicinity of the plant buildings or structures shall not constitute an attractant, breeding place or harborage for rodents, insects or other pests.

2. Roads, yards, and other parking lots shall be maintained so that they do not constitute a source of contamination to the bottled water.

3. Areas surrounding the plant shall be properly drained in order to prevent contamination of the bottled water by seepage, by foot-borne filth, or by providing a breeding place for rodents, insects or other pests.

(b) Plant buildings shall be of suitable size, construction, and design to facilitate maintenance and sanitary operations for processing purposes.

1. The bottle filling operations shall be separated from the balance of plant operations and storage areas by tight walls, ceilings, and self-closing doors or other appropriate barriers. No loading or unloading of trucks or other vehicles shall take place within an establishment unless acceptable segregation or isolation is accomplished.

2. Sufficient space shall be provided for such placement of equipment and storage of materials as is necessary for sanitary operations.

3. The plant shall be designed to reduce the potential for contamination of end products, raw materials, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be

reduced by any effective means including the separation by location, partition, air flow, enclosed systems or other effective means, of the plant operations to include receiving; raw material storage; processing operations; packaging and packing; finished product storage and shipping; portable equipment and utensil cleaning and sanitizing; and equipment and vehicle maintenance.

4. Floors, walls, and ceilings shall be constructed to be easily cleanable and shall be kept clean and in good repair. Fixtures, ducts, pipes shall be installed in such a manner that drip or condensation does not contaminate the bottled water, raw materials, or product contact surfaces. Aisles or walking spaces between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of the bottled water or product contact surfaces.

i. Floors, walls, and ceilings in the bottling room(s) shall be constructed of smooth, nonabsorbing, easily cleanable, light colored surface material and maintained in a clean and sanitary condition at all times.

ii. The floors in the bottling rooms shall be adequately drained in order to prevent pooling of water and to facilitate cleaning procedures. In addition, drain lines from equipment shall not discharge wastewater or product in such a manner as will permit flooding of floors or the flowing of water across working or walking areas or in difficult to clean areas or otherwise create a nuisance. Wastewater disposal shall be provided and have a discharge to a municipal wastewater system or an approved individual wastewater disposal system.

5. Adequate lighting shall be provided throughout the plant to facilitate cleaning and inspection procedures.

i. At least 30 foot candles of light shall be provided in the processing, bottling, equipment, and utensil washing areas. All other areas shall have a minimum of 10 foot candles of light at a distance of 30 inches from the floor surfaces.

ii. Light fixtures which are located in processing, equipment/utensil washing areas or other areas where bottled drinking water may be exposed shall be of the safety type, or otherwise protected to prevent contamination/adulteration in case of breakage.

6. Ventilation in every room of a plant or facility shall be adequate to minimize condensation, odors, vapors, noxious fumes, dust, and other potential airborne contaminants.

(c) Every plant and facility shall be provided with effective screening, rodent proofing, or other protective methods against animals and vermin.

1. No vermin or animal shall be permitted in the areas of a bottled water plant.

2. Effective measures shall be taken to exclude pests from processing areas and to protect against the contamination of the bottled water products.

3. The use of pesticides is permitted only under precautions and restrictions that will prevent contamination of the water. Pesticides shall be applied in an approved manner and by a certified applicator in conformance with the New Jersey Department of Environmental Protection Regulations, N.J.A.C. 7:30, Pesticide Control Regulations.

(d) The establishment shall be provided with adequate sanitary facilities and control measures to protect the purity and quality, of the bottled water. Facilities and controls shall include, but not be limited to:

1. The water supply shall be adequate as to quantity, of a safe, sanitary quality, and from a public or private water supply system which is constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act, N.J.S.A. 58:12A-1 et seq., N.J.A.C. 7:10, and local laws, ordinances, and regulations; provided, that if approved by the Department of Environmental Protection, a nonpotable water supply system may be permitted within the establishment for purposes such as air conditioning and fire protection, only if such system complies fully with the above referenced regulations and the nonpotable water supply is not used in such a manner as to bring it into contact, either directly or indirectly, with water processing or handling equipment.

i. Hot and cold running water, under sufficient pressure, shall be provided in all areas where bottled drinking water is processed and filled and where equipment, utensils, or containers are washed.

2. All plumbing shall be sized, installed and maintained in accordance with N.J.A.C. 5:23, New Jersey Uniform Construction Code and shall:

i. Carry adequate quantities of water to required locations throughout the establishment;

ii. Prevent contamination of the water supply;

iii. Properly convey sewage and liquid wastes from the establishment to the sewer or sewage disposal system; and

iv. Not constitute a source of contamination of water, equipment or utensils, or create an unsanitary condition or nuisance.

3. Nonpotable water shall not be connected to water related equipment or have outlets in the water processing areas. The potable water supply piping shall not be directly connected with any nonpotable water supply system whereby the nonpotable water can be drawn or discharged into the potable water supply system, provided, that an exception would be an approved physical connection conforming to N.J.A.C. 7:10-10, Safe Drinking Water regulations. The piping of any nonpotable system shall be adequately and durably identified, such as by a distinctive yellow colored paint, so that it can be readily distinguished from piping which carries potable water; and such piping shall not be connected to equipment or have outlets in the processing and bottling area.

4. All sewage and waste water shall be disposed of by means of:

i. A public sewerage system; or

ii. A disposal system which is constructed and operated in conformance with N.J.A.C. 7:9-2, Standards for the Construction of Individual Subsurface Sewage Disposal Systems, the New Jersey Water Pollution Control Act Regulations, N.J.A.C. 7:14, and local laws, ordinances, and regulations.

5. Each plant shall be provided with adequate, conveniently located toilet facilities accessible to the employees at all times.

i. Toilet facilities and dressing rooms, when provided, shall be installed in accordance with N.J.A.C. 5:23, New Jersey Uniform Construction Code.

ii. Doors to toilet rooms and dressing facilities shall be self-closing and shall not open directly into areas where product is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination.

iii. Toilet facilities and dressing rooms, including toilet rooms and fixtures, shall be kept clean and in good repair and free from objectionable odors.

iv. A supply of toilet tissue shall be provided at each toilet at all times.

v. Handwashing signs stating "Wash Hands Before Resuming Work" shall be posted conspicuously in all toilet rooms and at each separate lavatory facility in a bottling plant.

vi. Easily cleanable receptacles shall be provided for waste materials and such receptacles in toilet rooms for women shall be covered. Such receptacles shall be emptied at least once a day, and more frequently when necessary, to prevent excessive accumulation of waste material.

vii. Hot or cold or tempered (90 degrees to 105 degrees Fahrenheit) water under pressure shall be provided in toilet facilities.

6. Lavatories shall be adequate in size and number and shall be so located as to permit convenient and expeditious use by all employees.

i. Lavatories shall be installed in accordance with N.J.A.C. 5:23, New Jersey Uniform Construction Code.

ii. Each lavatory shall be designed to provide hot and cold or tempered (90 degrees to 105 degrees Fahrenheit) running water.

iii. An adequate supply of hand cleansing soap, detergent, or other sanitizing solution shall be available at each lavatory. Also, an adequate supply of sanitary towels, or an approved drying device, shall be available and conveniently located near the lavatory. Common towels are prohibited. Where disposable towels are used, waste receptacles shall be located conveniently near the handwashing facilities.

iv. Lavatories, soap dispensers, hand drying devices, and all other components of the handwashing facilities shall be kept clean and in good repair.

8:21-5.7 Production, equipment, and packaging requirements

(a) 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 undesirable bacterial or other microbiological growth, toxic formations, deterioration or contamination of the

processed product, production equipment, and product packaging materials and shall be in conformance with 21 CFR 129.1, 129.20, 129.30, 129.35, 129.37, 129.40, and 129.80, incorporated herein by reference.

(b) All water that is bottled shall receive a final disinfectant treatment that ensures a minimum 0.1 milligram per liter ozone residual or utilize other effective microbial control procedures at the time of packaging. Bottled water treated with ozone shall not exceed a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water as established under 21 CFR 184.1563. Test kits or other appropriate equipment shall be used to measure the disinfectant residual at least daily, or more frequently, if deemed appropriate by the Department.

(c) Water storage tanks shall be designed to exclude all foreign matter. All ports, hatches, and other openings shall be provided with tight fitting covers and shall be vented only through the use of inverted air filters or other approved venting device(s).

(d) Product water pipelines shall be constructed with seams and pipe connections that are smoothly bonded or connected to minimize the accumulation of scale residue or other contaminants.

1. Pipe connections shall be constructed for easy breakdown for inspection and cleaning.

2. Transport pipelines charging the storage tanks and transporting water to the filling lines shall be used only for bottled water products.

(e) All treatment and processing of bottled drinking water by distillation, ion-exchange, filtration, reverse osmosis, mineral addition, and ultraviolet treatment or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in conformance with Section 409 of the Federal Food, Drug, and Cosmetic Act.

(f) The filling and closing of bottled water containers shall be done in a sanitary manner by approved mechanical filling and capping equipment. Other sanitary methods may be approved by the Department.

1. Fillers shall have a charging inlet designed to prevent the entry of condensation and contaminants. All filling valves shall be equipped with a condensation diverting apron.

2. All closure hoppers and product reservoirs or filling machines as well as any other

type of hopper or conveying system used in the production and filling of bottled water products shall be equipped with covers. These covers shall adequately protect closures and bottled water from dust, dirt, and other contaminants and shall be in place at all times.

3. Fillers and other processing, filling and capping equipment used in the production of bottled drinking water shall be constructed of smooth, impervious, corrosion resistant nontoxic materials. All fillers shall be constructed for ease of cleaning and kept in good repair.

4. Fillers, filling line piping, pumps, and other processing, filling, and capping equipment used in the production of bottled water shall not be used for the production of milk, fruit drinks, and/or any other food products, unless adequate written washing and sanitizing procedures that shall prevent microbiological contamination or adulteration of the bottled water have been established and followed. Non-food products shall not be processed, filled, and/or capped on lines used for bottling water products.

5. Only sanitary, nontoxic, food grade lubricants shall be used on container contact surfaces.

(g) Containers and closures for bottled water shall conform to the requirements of 21 CFR 177, incorporated herein by reference.

1. All cleaned bottled water containers and single service containers shall be protected from dust, dirt, insects, debris, and all other forms of contamination while in storage or during production, filling and capping operations.

2. All closures (screw, snap, or crown caps) shall be new. These closures, while in storage, shall be covered and protected from contamination and/or adulteration at all times.

8:21-5.8 Sanitation and maintenance requirements

(a) All tanks, pipelines, and equipment used to store and transport water shall be inspected, maintained, cleaned, and sanitized. Sanitizing shall be accomplished by one of the following methods followed by a product water flush.

1. Chemical sanitizer shall be equivalent to a chlorine water solution of 50 parts per million for a minimum of two minutes at a temperature of 75 degrees Fahrenheit.

i. If surfaces cannot be reached by the aforementioned soaking treatment, surfaces shall be sprayed with 100 parts per million chlorine water solution at 75 degrees Fahrenheit.

ii. Other chemical sanitizers of equivalent concentration may be used provided they meet the equivalent concentrations as outlined in this subsection.

iii. Steam sanitization in an enclosed system of at least 170 degrees Fahrenheit for at least 15 minutes or 200 degrees Fahrenheit for five minutes.

iv. Hot water in an enclosed system of at least 170 degrees Fahrenheit for at least 15 minutes or at 200 degrees Fahrenheit for at least five minutes.

v. 0.1 parts per million ozone water solution for not less than a five minute contact time period.

(b) The following additional requirements shall apply to the cleaning, sanitizing, and monitoring of equipment.

1. Storage tanks shall be inspected on a monthly basis and shall be kept free of scale, evidence of oxidation, and residue.

i. Tank seams in contact with product water shall be smoothly bonded and maintained to minimize accumulation of possible contaminants.

ii. Tanks shall be cleaned and sanitized before use except that tanks that are used in a continuous production operation shall be cleaned and sanitized on a predetermined schedule with a minimum treatment of at least once a month.

2. Product water pipelines shall be kept free of scale, evidence of oxidation, and residue.

i. Product water pipelines shall be cleaned and sanitized before and after use and sanitizing shall be accomplished according to procedures outlined in this section.

3. Processing equipment, to include water treatment systems, shall be cleaned and sanitized in a manner and at a frequency so as to be effective in accomplishing its intended purpose(s). Cleaned and sanitized equipment and utensils when not in use shall be stored in a location and in a manner that protects product contact surfaces from splash, dust, dirt, and any other type of possible contamination.

i. Water treatment equipment to include ozone mixing tanks and equipment, soft water tanks, and all associated equipment shall be inspected on a monthly basis, disassembled, if necessary; cleaned; and sanitized.

ii. Bottle washing equipment shall be kept free of paper residue and substances which may interfere with the proper operation of the water or air jets. Internal sprays shall be checked on a daily basis to assure proper timing and adequate dispersion of the washing medium to properly clean the containers.

iii. Fillers shall be kept free from scale, evidence of oxidation and residue, and shall be sanitized before and immediately after use.

(1) The filler reservoir shall be kept adequately covered at all times.

(2) Filling and capping operations shall be conducted as to prevent contamination of the water being bottled.

iv. Cappers shall be kept free of residue and washed, rinsed, and sanitized before and after use.

(1) Capper hoppers shall be kept adequately covered to protect the closures from dust, dirt, and other contaminants and shall be emptied when not in use.

(2) Hopper surfaces in contact with product container closures shall be kept free of residue and sanitized before and after use.

8:21-5.9 Storage and handling of chemicals

(a) The following requirements shall apply to the storage and handling of chemicals:

1. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended use.

2. Only toxic materials that are required to maintain sanitary conditions in laboratory testing procedures, for plant and equipment maintenance and operations or in manufacturing or processing operations shall be used and stored in the facility.

3. Poisonous or dangerous cleaning compounds, sanitizing agents, and pest control chemicals shall be applied, stored, and held in a manner that prevents the raw water, bottled water, or water packaging materials and equipment from being contaminated.

4. These materials shall be identified and used only in the manner and under the conditions that will be safe for their intended use.

8:21-5.10 Personnel requirements

(a) All persons, while working in the processing and bottling of water, shall conform to good hygienic practices while those persons are on duty, to the extent necessary to prevent contamination of bottled water. The methods for maintaining cleanliness shall include, but are not limited to:

1. Wearing clean outer garments;

2. Maintaining a high degree of personal cleanliness;

3. Washing hands and exposed arms thoroughly with soap and warm water before starting work, after each absence from work station, after smoking, eating, drinking, or visiting the toilet room and at any other time when the hands may have become soiled or contaminated;

4. Removing all insecure jewelry and during periods in which the latter is manipulated by hand, removing from hands any jewelry that cannot be adequately sanitized;

5. If gloves are used in water bottling operations, they shall be maintained in a clean and sanitary condition;

6. Wearing hair nets, headbands, caps, beard covers, or other effective hair restraints in an effective manner;

7. No storing of clothing or other personal belongings in bottled water processing areas or in areas used for washing equipment or utensils;

8. No eating of food, drinking of beverages, expectorating, or using tobacco in areas where water is being processed or bottled or in areas used for washing of equipment or utensils; and

9. Taking any other necessary precautions to prevent contamination of bottled water with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines.

(b) No person shall be allowed to live or sleep in any room where bottled water is produced, manufactured, packed, stored, bottled, distributed, or sold.

(c) 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 in which 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.

8:21-5.11 Sanitizing requirements for multi-use bottles or containers

(a) Mechanical bottle washers shall be provided when multi-use containers are used. In addition, mechanical washers shall be designed and maintained to thoroughly wash and sanitize all surfaces of containers prior to filling.

(b) Multi-use bottles shall be checked prior to washing by a method acceptable to the Department to assure that containers that may have been used for other purposes are not reused for bottled water. Such containers shall be rendered unusable for rebottling.

(c) 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 product water to remove traces of sanitizing agents.

(d) The bactericidal procedure as a minimum, shall be one of the following:

1. Sanitize with 100 parts per million chlorine water solution at 75 degrees Fahrenheit for not less than 30 seconds;

2. Sanitize with a 2½ percent caustic solution at a minimum temperature of 120 degrees Fahrenheit followed by a rinse containing not less than 10 parts per million free chlorine. (Note: When caustic is discharged by means of high-velocity jets, this procedure shall be considered to satisfy both cleaning and bactericidal requirements);

3. Sanitize with water at an inside bottle temperature 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 means of automatic bottle washers utilizing high-velocity jets (hydro type) or by means of soaker washers, followed by a rinse

containing not less than 10 parts per million free chlorine;

5. As an alternative to the use of a caustic alkali solution, multi-use containers may be cleaned and sanitized prior to refilling by the use of an alkaline detergent cleaner containing a minimum of 0.35 percent active alkalinity at a minimum temperature of 130 degrees Fahrenheit for not less than one minute (if high velocity jets are used), or for not less than three minutes (if a soaker type washer is used), followed by a rinse of at least one minute with a sanitizing solution containing at least 25 parts per million chlorine or 10 parts per million iodine. All bottles and carboys shall be rinsed until free of any detergent or sanitizing solution residue with product water; or

6. Other methods equally protective of public health as the above, when approved by the Department, may be used.

(e) Only sanitizers listed in 21 CFR 178.1010 shall be acceptable.

8:21-5.12 Bulk water facility requirements

(a) Tank trucks, loading and unloading facilities, storage tanks, and other equipment used to store or transport bulk water shall be maintained in a clean and sanitary condition. All previously cited rules and regulations which pertain to equipment, construction, maintenance, cleaning, and sanitizing shall also apply to transporting and handling of bulk water.

(b) All sources of water for bulk water shipment must be approved by the New Jersey Health Department or the governmental regulatory agency having jurisdiction over the source water location outside the State or in a foreign country. Before bulk water is delivered to any bottling plant, an analysis of the water indicating that it meets bacteriological, chemical, and radiological standards set forth in this subchapter shall be submitted to the plant owner or operator.

(c) Tank trucks previously used to transport toxic substances, petroleum products, or other deleterious substances shall not be used to transport bulk water.

(d) Tank trucks and related equipment used to transport or handle bulk water shall be used for no other purpose and shall be thoroughly cleaned and sanitized prior to filling in accordance with the

provisions of N.J.A.C. 8:21-5.8 and shall comply with the following:

1. Storage tanks and tank trucks shall be free of deep pits, excessive scale, dents or poorly welded seams which may tend to hold standing water;

2. Inlets, outlets, piping hose and other appurtenances associated with storage tanks and tank trucks shall be constructed and handled to prevent contamination of product water;

3. All tank trucks shall be tagged identifying the time and place of cleaning and sanitization. These records shall be available at all times for inspection by the regulatory authority; and

4. All hoses, connections and fittings used in conjunction with the coupling of the tank truck to the bulk water delivery line shall be sanitized with 100 parts per million chlorine solution at 75 degrees Fahrenheit or any other approved sanitizer of equivalent concentration. The solution shall be brushed on all exposed parts to assure proper sanitization.

(e) The physical water quality in the tank truck shall be determined in the following manner:

1. At the time of filling of a tank with bulk water for transport, the tank truck shall be visually inspected and initially be filled with approximately 50 gallons of water. The discharge valve shall then be opened and several gallons of water discharged and checked for odor, clarity and particulates. If the water has an unsatisfactory odor, clarity or other detectable problem the tank truck shall be rejected. If satisfactory, the tank truck may be loaded for transport;

2. At time of delivery of bulk water to the bottling plant, the discharge valve of the tank truck shall be opened and several gallons shall be discharged and checked for odor, clarity and particulate matter. If the water has an unsatisfactory odor, clarity or other detectable problem the load shall be rejected;

3. The dome cover shall be opened at the time of filling and discharge of bulk water from the tank truck. The dome screen filter shall be in place and properly sealed during loading and unloading of tank trucks. Tank trucks shall be loaded and unloaded through the tail pipe discharge valve whenever possible; and

4. The dome cover and tail pipe valve cover and doors shall be closed prior to transport of water.

(f) The Department of Health shall be notified by telephone by the management of the water establishment anytime a tank truck or load of water is rejected at the time of pickup or delivery with the reason for rejection. This notification shall take place no later than the next business day.

8:21-5.13 Recordkeeping requirements

(a) Each bottling plant shall keep true and accurate records of all water processed. Such records shall show:

1. Source, type, and volume of water processed daily; and

2. Records indicating the physical inspection of bulk water delivered.

(b) Each bottling plant shall keep true and accurate records of finished product. Such records shall show:

1. The amount bottled;
2. Dates of bottling; and
3. Expiration date.

(c) Records of the required water analysis on both raw and finished product water as specified in N.J.A.C. 8:21-5.12 and 5.14 shall be forwarded to the Department. Upon completion, the certified laboratory conducting the required tests may, upon written approval of the Department, submit the test results on behalf of the plant owner or operator. The weekly microbiological test results may be consolidated and reported on a monthly basis.

(d) Records shall be kept of the cleaning and sanitizing of multipurpose fillers and bottle washing equipment, if applicable.

(e) All records shall be maintained at the plant for 30 months from the date of processing of the raw water and shall be available for review by the inspecting agency upon request.

8:21-5.14 Water standards and sampling requirements

(a) Bottled water which is manufactured, distributed, or sold within this State shall comply with the microbiological, physical, chemical, hazardous contaminants, and radiological standards set forth in the New Jersey Safe Drinking Water Act

rules under N.J.A.C. 7:10 except the following standards:

Lead – 5 parts per billion (ppb)

Copper – 1,000 parts per billion (ppb)

Total Coliform – none present

Turbidity – 5 nephelometric turbidity units (NTU)

(b) Bottlers and bulk water handling facilities which derive their water from a public community water system as defined under N.J.A.C. 7:10-1.3 are exempt from sampling the source (raw) water.

(c) Analysis shall be conducted in accordance with procedures set forth at N.J.A.C. 7:18, Rules Governing Laboratory Certification and Standards of Performance, and the following:

1. Microbiological Standards: A weekly analysis for total coliform shall be required for finished product water and for source (raw) water.

2. Physical Standards: An annual analysis shall be required for both source (raw) and bottled water.

3. Chemical Standards: An annual analysis shall be required for both source (raw) and bottled water.

4. Radiological Standards: A radiological analysis shall be required once every four years for both source (raw) and bottled water.

5. Hazardous Contaminant Standards: An annual analysis shall be required for selected hazardous contaminants as specified at N.J.S.A. 58:12A-13a, for which the New Jersey Department of Environmental Protection has established Maximum Contaminant Levels (MCL) standards under N.J.A.C. 7:10.

(d) If any bottled water standard for physical, chemical, microbiological or radiological quality is exceeded, the product shall be labeled with a statement indicating substandard quality as follows:

1. "Excessively Turbid," "Abnormal Color," and/or "Abnormal Odor" if the bottled water fails to meet any of the physical quality standards set forth in this section;

2. "Contains Excessive _____," with the blank filled in with the name of the chemical if the bottled water fails to meet any of the chemical quality standards set forth in this section. For example, "Contains Excessive Arsenic" or "Contains Excessive Trihalomethanes", except that "Contains Excessive Chemical

Substances" may be used if the bottled water is not mineral water;

3. "Excessively Radioactive" if the bottled water fails to meet the requirements of this section; and/or

4. "Contains Excessive Bacteria" if the bottled water fails to meet the microbiological standards set forth in this section.

(e) Bottled water containing a substance at a level considered injurious to health shall be deemed adulterated under N.J.S.A. 24:5-5, regardless of whether or not the bottled water bears a label statement of substandard quality prescribed in this section.

(f) The statement of substandard quality shall appear on the principal display panel or panels and shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the type of bottled water.

(g) The Department may require the owner/operator of the bottled water facility to institute additional treatment in order to meet bottled water standards when a maximum contaminant level is exceeded. If contamination is excessive and the best available treatment will not result in meeting the maximum contaminant level, the water supply shall be deemed adulterated and its use prohibited.

8:21-5.15 Bottled water certification requirements

(a) Every bottling plant and/or bulk water handling facilities including out-of-State or foreign bottling plants and/or bulk water handling facilities, that sell or distribute bottled and bulk water in New Jersey shall apply to the Department annually for a bottled water certification.

(b) In order for a bottling plant to obtain a certification from the Department to sell or distribute bottled water, the following requirements shall be met:

1. The applicant shall complete a certification application provided by the Department and provide the following information: the name and location of the bottling company, including the mailing address, telephone number and trade name of the bottling company or bulk water facility; the name of the water source, the name of the owner of the water source, the location and type of source(s), that is, well, spring, public community water system; the type and brand names of water being bottled, including the

container size(s) being bottled; and the annual production and the maximum monthly production in gallons. Bulk water companies shall provide information regarding the method of conveyance of bulk water. The applicant shall also provide the name and address of the New Jersey certified laboratory that is used to conduct the applicant's analysis. The names and addresses of companies in New Jersey used to distribute products shall be provided. The applicant shall provide a description of the water treatment process. The name of the inspecting agency and the date of the last inspection shall also be provided by out-of-State bottlers. The application shall be signed by the owner or operator responsible for the facility.

2. Out-of-State bottlers shall submit a letter of certification from the appropriate regulatory agency having jurisdiction over the operation verifying that the source supply and the facility has been inspected and is approved and ground water supplies have been evaluated for surface water influences under criteria equivalent to those established under N.J.A.C. 8:21-5.3(b).

3. A copy of each product label shall be submitted for each size and type of bottled water that will be sold or distributed. This requirement does not apply to bulk water.

4. A complete microbiological, physical, chemical, radiological, and hazardous contaminants analysis for all contaminants that have standards established under N.J.A.C. 7:10 must be performed on each source and type of finished bottled water product distributed in New Jersey. A copy of the required analyses shall accompany the application and shall be forwarded to the Department at the frequency prescribed in N.J.A.C. 8:21-5.14 except that microbiological sample results need only be submitted every six months.

5. All analyses required shall be conducted at an approved laboratory certified by the New Jersey Department of Environmental Protection in accordance with N.J.A.C. 7:18, Rules Governing Laboratory Certification and Standards of Performance, and the laboratory shall be certified for the specific method for which the water is being analyzed.

6. All analyses shall be performed within six months prior to the date of filing an initial certification application.

7. All bottlers shall submit an initial certification application and initial filing fee each

time there is a change or addition of a source of water. The bottler shall submit the required information for the new source delineated under this section for each new source of supply.

(c) In order to obtain a certification to sell or distribute bulk water, the following requirements shall be met:

1. The applicant shall comply with (a) and (b) above required for bottled water plant certification except for (a)3 above concerning label submissions;

2. The establishment shall comply with all of the provisions of N.J.A.C. 8:21-5.12, Bulk water facility requirements;

3. A complete microbiological, physical, chemical, radiological, and hazardous contaminants analysis must be performed on each source of water that is used in accordance with the standards established under N.J.A.C. 8:21-5.14. Sample results must be submitted initially with the application for registration and annually thereafter; and

4. The bulk water facility shall submit an initial certification application and initial filing fee to the Department any time there is a change in the source of bulk water. The establishment shall meet all of the criteria of this section before resuming bulk shipments of water into New Jersey.

8:21-5.16 Certification fees

(a) The Department shall collect from each applicant a certification fee in the following amount:

1. For an initial certification application, \$1,000 for each source of supply; and

2. For an annual renewal application, \$650.00 for each source of supply.

8:21-5.17 Exemptions

(a) Pursuant to N.J.S.A. 24:12-5, water bottling plants located in New Jersey are exempted from the requirement to pay a bottling plant license fee of \$50.00.

(b) A water bottling plant receiving a source of supply from a bulk water facility that holds a valid certification issued by the Department is exempt from paying a certification fee for that source of supply.

**8:21-5.18 Expiration of certification;
nontransferability of certification**

(a) Upon approval of the application for certification, and of the sanitary conditions, test results, product labels and receipt of letter of inspection for out-of-State bottlers/bulk water facilities and upon payment of the required certification fee, the Department shall issue each applicant a certification that expires on June 30 of each year.

(b) The certification issued pursuant to (a) above shall not be transferable with respect to persons or locations.

8:21-5.19 Revocation of certification

(a) Upon evidence duly ascertained by the Department or furnished to the Department by a regulatory agency having jurisdiction over bottled water for out-of-State sources that the person holding a certification issued under the provisions of these rules is violating any of these rules or statutes as hereinbefore provided, the Department shall, upon a hearing and proof of allegation, revoke the certification. The hearing shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(b) No certification shall be renewed or restored until the Department is satisfied that all provisions of the law and pertinent rules are complied with.

(c) The Department, to protect the public health, may, before a hearing, suspend such certification pending the hearing. It shall be unlawful for the suspended certificate holder to engage in the business for which the certification was granted during such period of suspension. Upon written request, the certificate holder will be granted an expedited hearing conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the Uniform Administrative Procedures Rules, N.J.A.C. 1:1.