



# *Rhode Island Department of Health*

## **PUBLIC NOTICE**

The Director of the Rhode Island Department of Health has determined to amend the rules and regulations listed below to remove the specific dollar value of all fees for licensing, laboratory and administrative services provided by the Department of Health from the individual regulations and reference all such fees to a new consolidated fee regulation (to be promulgated separately). These amendments are proposed pursuant to the authority contained in Public Law 2012-241, enacted by the General Assembly on 15 June 2012, and the relevant sections of the respective professional practice and licensure acts.

### **The following seventy-five (75) regulations are proposed to be amended:**

1. Food Code
2. Rules and Regulations Establishing Educational and Experience Requirements for Registration as a Sanitarian
3. Rules and Regulations for Asbestos Control
4. Rules and Regulations for Bottled Water
5. Rules and Regulations for Certifying Analytical Laboratories
6. Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services
7. Rules and Regulations for Lead Poisoning Prevention
8. Rules and Regulations for Licensing Assisted Living Residences
9. Rules and Regulations for Licensing Athletic Trainers
10. Rules and Regulations for Licensing Birth Centers
11. Rules and Regulations for Licensing Chemical Dependency Professionals
12. Rules and Regulations for Licensing Clinical Laboratories and Stations
13. Rules and Regulations for Licensing Clinical Social Workers and Independent Clinical Social Workers
14. Rules and Regulations for Licensing Doctors of Acupuncture and Acupuncture Assistants
15. Rules and Regulations for Licensing Home Nursing Care Providers and Home Care Providers
16. Rules and Regulations for Licensing Hospice Care
17. Rules and Regulations for Licensing Interpreters for the Deaf
18. Rules and Regulations for Licensing Kidney Disease Treatment Centers
19. Rules and Regulations for Licensing Massage Therapists
20. Rules and Regulations for Licensing Mental Health Counselors and Marriage and Family Therapists
21. Rules and Regulations for Licensing Occupational Therapists and Occupational Therapy Assistants
22. Rules and Regulations for Licensing of Hospitals
23. Rules and Regulations for Licensing of Midwives
24. Rules and Regulations for Licensing of Nursing Facilities
25. Rules and Regulations for Licensing of Nursing Home Administrators
26. Rules and Regulations for Licensing Physical Therapists and Physical Therapist Assistants
27. Rules and Regulations for Licensing Psychologists
28. Rules and Regulations for Licensing Rehabilitation Hospital Centers

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29. Rules and Regulations for Licensing Respiratory Care Practitioners
30. Rules and Regulations for Licensing Speech Pathologists and Audiologists
31. Rules and Regulations for Licensing Swimming and Wading Pools, Hot Tubs, and Spas
32. Rules and Regulations for Licensure and Discipline of Chiropractic Physicians
33. Rules and Regulations for Limited Medical Registration
34. Rules and Regulations for Radon Control
35. Rules and Regulations for the Certification of Administrators of Assisted Living Residences
36. Rules and Regulations for the Certification of Health Plans
37. Rules and Regulations for the Control of Radiation
38. Rules and Regulations for the Licensing of Freestanding Ambulatory Surgical Centers
39. Rules and Regulations for the Licensing of Freestanding Emergency Care Facilities
40. Rules and Regulations for the Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs
41. Rules and Regulations for the Licensing of Nursing Service Agencies
42. Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities
43. Rules and Regulations for the Licensing of Podiatrists
44. Rules and Regulations for the Licensing of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants
45. Rules and Regulations for the Licensure and Discipline of Physicians
46. Rules and Regulations for the Licensure of Barbers, Hairdressers/Cosmeticians, Manicurists, Estheticians, and Instructors
47. Rules and Regulations for the Licensure of Clinical Laboratory Science Practitioners
48. Rules and Regulations for the Licensure of Physician Ambulatory Surgery Centers and Podiatry Ambulatory Surgery Centers
49. Rules and Regulations for the Licensure of Physician Assistants
50. Rules and Regulations for the Licensure of Veterinarians
51. Rules and Regulations for the Registration of Body Piercing Technicians and Body Piercing Establishments
52. Rules and Regulations for the Registration of Distributors of Controlled Substances in Rhode Island
53. Rules and Regulations for the Registration of Tanning Facilities
54. Rules and Regulations for the Registration of Tattoo Artists and Tattoo Parlors
55. Rules and Regulations for the Utilization Review of Health Care Services
56. Rules and Regulations Governing Vital Statistics
57. Rules and Regulations Pertaining to Certification of Managers in Food Safety
58. Rules and Regulations Pertaining to Dentists, Dental Hygienists, and Dental Assistants
59. Rules and Regulations Pertaining to Embalmers, Funeral Directors, and Funeral Service Establishments
60. Rules and Regulations Pertaining to Opticians
61. Rules and Regulations Pertaining to Optometrists
62. Rules and Regulations Pertaining to Permits for Screening Programs
63. Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors
64. Rules and Regulations Pertaining to Public Drinking Water
65. Rules and Regulations Pertaining to Rhode Island Certificates of Registration for Nursing Assistants, Medication Aides, and the Approval of Nursing Assistant and Medication Aide Training Programs
66. Rules and Regulations Pertaining to the Certification of Public Drinking Water Supply Treatment and Public Water Supply Transmission and Distribution Operators

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67. Rules and Regulations Pertaining to the Licensing of Dietitians/Nutritionists
  68. Rules and Regulations Pertaining to the Medical Examiner System
  69. Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program
  70. Rules and Regulations Pertaining to the Processing and Distribution of Shellfish
  71. Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products
  72. Rules and Regulations Related to the Licensure of Hearing Aid Dealers and Fitters
  73. Rules and Regulations Related to the Medical Marijuana Program
  74. Rules and Regulations Related to the Practice of Electrolysis
  75. Rules and Regulations Relating to Emergency Medical Services
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Notice is hereby given in accordance with the provisions of §42-35-3(a)(2) of the Rhode Island General Laws, as amended, that the Director is affording all interested persons the opportunity to submit data, views, or arguments in writing on this matter. Opportunity for public hearing shall be granted if requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members. *Otherwise, no hearing shall be convened.* Should a hearing be requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members, *a hearing shall be scheduled only for the regulation(s) for which the request for hearing was received.* All regulations for which a public hearing is not requested will be filed with the Rhode Island Secretary of State pursuant to Chapter 42-35 of the Rhode Island General Laws, as amended, shortly after the **10 September 2012** deadline (as below).

Such input or requests for public hearing must be received in writing **no later than Monday, 10 September 2012**. Such input or requests should be addressed to: Michael Fine, M.D., Director, Rhode Island Department of Health, Three Capitol Hill, Room #401, Providence, Rhode Island 02908-5097.

In the development of these amendments, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach, duplication, or overlap was identified based upon available information.

Copies of all regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, Three Capitol Hill, Providence, Rhode Island 02908-5097, on the Secretary of State's website: <http://www.sos.ri.gov/rules/>, by calling 401-222-7767, or by e-mail to [Bill.Dundulis@health.ri.gov](mailto:Bill.Dundulis@health.ri.gov).

Signed this 3<sup>rd</sup> day of August 2012

*Original signed by Michael Fine, MD*

Michael Fine, M.D., Director of Health

# RULES AND REGULATIONS FOR BOTTLED WATER

[R21-23-BB]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

August 1987

## ***AS AMENDED:***

August 1987

December 1987 (E)

March 1988

December 1991 (Bottled Water Only)

January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

December 2011 (E)

January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

April 2012 (E)

**August 2012 (Proposed)**

## **COMPILER'S NOTES:**

**Proposed Additions:** Underlined

**Proposed Deletions:** ~~Strikeouts~~

## ***INTRODUCTION***

These amended *Rules and Regulations for Bottled Water* are a sub-part of the *Rules and Regulations for Non-Alcoholic Bottled Beverages, Drinks and Juices [R21-23-BB]*, promulgated pursuant to the authority set forth in Chapter 21-23 of the General Laws of Rhode Island, as amended, for the purpose of adopting unified definitions to be applied to those appropriate parts of subchapter B - Food for Human Consumption of Chapter 1, Food and Drug Administration, U.S. Department of Health and Human Services (Revised as of April, 1987); and other references as indicated in these regulations.

In accordance with the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, consideration was given to (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) and significant economic impact on small business as defined in Chapter 42-35 of the General Laws. Based on available information, no known alternative or duplication was identified. The health and safety of the public supersedes any economic impact.

These amendments replace appropriate sections of Part 101 -entitled Food Labeling which pertains to nonalcoholic bottled beverages, drinks and juices, and Part 129- entitled Processing and Bottling of Bottled Drinking Water of the Code of Federal Regulations, dated April 1, 1987, and filed with the Secretary of State on March 14, 1988.

These amended regulations shall supersede all previous *Rules and Regulations for Bottled Water* promulgated by the Rhode Island Department of Health and filed with the Secretary of State.

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## PART I      **DEFINITIONS**

### Section 1.0    *Definitions*

Wherever used in the *Rules and Regulations for Bottled Water* the following terms shall be construed as follows:

- 1.1    *"Approved Laboratory"* means a laboratory approved by the Director or certified by the U.S. Environmental Protection Agency (EPA), or certified by the primary enforcement authority in any state which has been granted primacy by EPA, or certified (accredited) by a third-party organization acceptable to a primacy state.
- 1.2    *"Approved Source"* when used in reference to a bottled water plant's product water or water used in the plant's operation, means the source of the water whether it be from a spring, artesian well, drilled well, public or community water system or any other source that has been inspected and the water sampled, analyzed and found to be of a safe and sanitary quality, according to standards approved by the Director.
- 1.3    *"Artesian Water"* means bottled water from a well tapping a confined aquifer in which the water level stands above the water table. "Artesian Water" shall meet the requirements of "Natural Water".
- 1.4    *"Bottled Drinking Water"* means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including mineral water and spring water sometimes referred to as product water.
- 1.5    *"Bottled Water Plant"* means any place or establishment in which bottled water is prepared for sale.
- 1.6    *"Bulk Water"* shall mean water intended for potable uses which is transported by means of tank trucks, for use in bottling only.
- 1.7    *"Carbonated Water"* or *"Sparkling Water"* means bottled water containing carbon dioxide.
- 1.8    *"Dedicated"* shall mean equipment used exclusively for the bottling, manufacturing and processing of water.
- 1.9    *"Director"* means the Director of Health of the Rhode Island Department of Health.
- 1.10    *"Distilled Water"* means bottled water which has been produced by a process of distillation and meets the definition of purified water in the most recent edition of the United States Pharmacopeia.
- 1.11    *"Fluoridated Water"* means bottled water containing fluoride. The label shall specify whether the fluoride is naturally occurring or added. Any water which meets the definition of this subsection shall contain not less than 0.8 milligrams per liter fluoride ion and otherwise comply with the Food and Drug Administration (FDA) quality standards in §165.10(b)(4)(ii) of Title 21 Code of Federal Regulations (CFR).

- 1.12 *"Food and Drugs CFR"* shall mean the code of Federal Regulations, Title 21, Food and Drugs.
- 1.13 *"Lot"* means a collection of primary containers or unit packages of the same size, type and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.
- 1.14 *"Mineral Water"* means water that is impregnated with mineral solids and has been obtained entirely from an approved source. It shall contain not less than 500 parts per million (ppm) of dissolved mineral solids.
- 1.15 *"Multi-use Containers"* or *"multi-service containers"* shall mean those containers which are intended by the bottler for more than one use.
- 1.16 *"Natural Water"* means bottled spring, mineral, artesian or well water which is derived from an underground formation and is not derived from a municipal system or public water supply.
- 1.17 *"Nontoxic Materials"* shall mean transporting, storing and packaging materials 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 product.
- 1.18 *"Operations Water"* means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.
- 1.19 *"Purified Water"* means bottled water produced by distillation, deionization, reverse osmosis or other suitable process and that meets the definition of purified water in the most recent edition of the United States Pharmacopeia.
- 1.20 *"Sample"* means a unit of equal volume which is analyzed by a consistent method and measured against a standard.
- 1.21 *"Spring Water"* means water derived from an underground formation from which water flows naturally to the surface of the earth.
- 1.22 *"Sanitizing"* means the cleaning and disinfecting of products used for bottling and/or surfaces of equipment used for the operating and/or manufacturing of bottled water products to prevent a potential health hazard, or source of contamination.
- 1.23 *"Trihalomethane"* (THM) means one of a family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.
- 1.24 *"Well Water"* means water from a hole bored, drilled or other wise constructed in the ground which taps the water of an aquifer. "Well Water" shall meet the requirements of "Natural Water".

## PART II      **STANDARDS OF QUALITY**

### Section 2.0      *Standards of Quality*

- 2.1      (a) All bottled water shall be from an approved source and shall meet standards prescribed by the FDA in 21 CFR, §165.10, except that the total dissolved solids limitation of §165.10(b)(4)(i)(A) shall not apply to mineral water.

Analysis of samples taken to determine quality may be performed for the plant by approved laboratories as defined in section 1.1

- (b) Except as provided in subsection (a), bottled water, including mineral water, shall not exceed any standard contained in Appendix I, hereto, or any standard established by State Rules and Regulations Pertaining to Public Drinking Water (R46-13-DWQ).

### 2.2      **Adulteration.**

Bottled water containing a substance at a level considered injurious to health is deemed to be adulterated, regardless of whether or not the bottled water bears a label statement of substandard quality.

### Section 3.0      *Sources of Water*

- 3.1      The sources of all bulk or bottled drinking water located in Rhode Island must be approved by the Director. Sources of all bottled drinking water located outside of Rhode Island must be approved by the agency having jurisdiction.

#### 3.1.1      **General Source Requirements:**

- (a) Routine chemical, physical, radiological, and bacteriological monitoring of all source waters is essential for public health protection. The untreated waters of the source shall be sampled to characterize raw water bacteriological, physical, radiological and chemical quality at the minimum frequency prescribed by the Director. See APPENDIX I, TABLE I - BOTTLED WATER SAMPLING REQUIREMENTS.
- (b) Unusual source and source development proposals shall be submitted to the Director before such sources are developed.
- (c) Operations water, if different from the product water supply shall be obtained from an approved source properly located protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations.

#### 3.1.2      **Maintenance and Construction**

- (a) Springs, as a minimum, shall have:
- (i) A watertight wall completely surrounding the spring, not less than 12" above the highest point of the ground, and extending down through the overburden to the water bearing stratum. The top of the wall shall be level to accommodate a cover.

- (ii) A wall keyed and sealed with cement grout to the rock.
  - (iii) A tight fitting locked cover installed on the top of the encircling wall to protect against contamination.
  - (iv) Surface water diverted away from the spring by means of a ditch or berm.
  - (v) Spring water collected only at the natural orifice of the spring or through a bore hole that is adjacent to it. Spring water that is collected with external assistance 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.
- (b) Drilled wells, as a minimum shall
- (i) have watertight casings to the depth necessary to prevent surface and/or strata contamination.
  - (ii) Have a permanent casing at least 12 inches above the pumphouse floor or concrete apron surface and at least 18 inches above final ground surface. All well pits must have a gravity drain that discharges to grade.
  - (iii) Be located on sites not subjected to flooding , or have other suitable protection as determined by RIDOH.
  - (iv) Be equipped with an approved pitless adaptor unit installed at the joint where the discharge pipe passes through the well casing.

### 3.1.3 **New Water Sources**

- (a) New sources shall be in compliance with those requirements as found in Rules and Regulations Pertaining to Public Drinking Water (R46-13-DWQ.)
- (b) No source of water shall be developed for a water bottling manufacturing/ processing system until a site plan is prepared by a professional engineer or land surveyor registered in accordance with Chapter 5-8 of General Laws of Rhode Island, 1956, as amended, has been approved by the Director.
  - (i) The site plan shall include an appropriately scaled topographic map of the area under consideration.
  - (ii) Approval of plans and specifications granted an applicant shall expire within two years if construction of the approved source has not begun within that period.
  - (iii) Expired approvals may be renewed if the data provided in the application is unchanged and attested to by the applicant and the plans conform with all construction standards and testing requirements in effect at the time of application for renewal.
- (c) In the case of a proposed gravel packed or gravel developed well, the site plan shall contain pertinent information within at least 1,750 feet of the proposed well including, but not limited to, the location of existing and proposed sewage disposal systems and any other existing or proposed potential sources of

pollution including, but not limited to those listed in Appendix 3 of the State Rules and Regulations Pertaining to Public Drinking Water (R46-13-DWQ). Generally, the land within 400 feet of such wells shall be reserved for protection of the water quality of the well. This distance may be modified at the discretion of the director taking into consideration such factors as the volume and type of waste material to be disposed or stored in close proximity to the land area reserved for protection of the well, the projected yield of the well, the depth below grade to impervious formation, the depth below grade to the water table, the type of soil in the area, or any other factors the director deems pertinent.

- (d) In the case of a proposed drilled (rock), driven, or dug well, the site plan shall show pertinent information within at least 1,750 feet of the proposed well including, but not limited to, the location of existing and proposed sewage disposal systems and any other existing or proposed potential sources of pollution including, but not limited to those listed in Appendix 3 of the State Rules and Regulations Pertaining to Public Drinking Water (R46-13-DWQ). Generally, the land within 200 feet of such wells shall be reserved for protection of the water quality of the well. This distance may be modified at the discretion of the director taking into consideration such factors as the volume and type of waste material to be disposed or stored in close proximity to the land area reserved for protection of the well, the depth below grade to impervious formation, the depth below grade to the water table, the type of soil in the area, or any other factors the director deems pertinent.
- (e) In the case of a proposed surface water source, the site plan shall show pertinent information within the entire watershed of the proposed surface water supply, but not limited to the location of existing and proposed sewage disposal systems and any other existing or proposed potential sources of pollution including but not limited to those listed in Appendix 3 of the State Rules and Regulations Pertaining to Public Drinking Water (R46-13-DWQ). The portions of the watershed owned or controlled by the water purveyor shall be clearly indicated. All surface water sources shall be provided with water treatment consisting, as a minimum, of coagulation, sedimentation, filtration and disinfection.
- (f) All revisions to approved plans must be submitted to the Director for approval. The Director may require a new application and/or site plan if the revisions are deemed significant.

#### Section 4.0 *Treatment of Product Water*

- 4.1 All treatment of product water by distillation, ion-exchanging, filtration, ozonation ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment shall

be maintained by the plant.

- 4.1.1 Product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant.
- 4.1.2 The methods of analysis shall be those approved by the Director.

## Section 5.0 ***Bottling Plant Facilities***

- 5.1 Bottling plants must be constructed to facilitate cleanliness, and be maintained to maximize sanitation and public health protection.
- 5.2 Minimum Structural Requirements shall include no less than the following:
  - (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 building 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 condensation 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, adequate for operations, with a minimum of 50 foot candles at the working surface, in all rooms where bottled or packaged waters are produced. 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 product contamination.
  - (i) Clean, dry storage facilities shall be provided for product containers and packaging materials.
  - (j) 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.

- (k) When employee locker and lunchrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be maintained in a clean and sanitary condition and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

## Section 6.0 ***Production, Equipment and Packaging***

- 6.1 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 substance formation, deterioration or contamination of the processed product.
  - 6.1.1 During the process of filling, capping or sealing either single service or multiservice containers, the performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped and sealed, coded and labeled.
  - 6.1.2 Fillers, piping, pumps and other process equipment used in the production of bottled water products may not be used for the production of milk, fruit drinks and/or any other beverage, food or non-food substance.

### 6.2 **Minimum Equipment Requirements:**

All equipment shall be of sanitary design and shall be constructed of nontoxic, nonabsorbent materials 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 all adjacent spaces.

- 6.2.1 Storage tanks used for bottled water production shall be:
  - (a) tightly closed to exclude all foreign matter and vented through inverted approved air filters;
  - (b) without connections to supplies of water not approved by the Director;
  - (c) protected from cross connection and equipped with backflow prevention devices approved by the Director;
  - (d) equipped with linings or coatings conforming to the listing of acceptable linings for process and potable water tanks from the Director;
  - (e) used only for water and not for storage of any other food product or non-food substance.
- 6.2.2 All pipelines and valves shall have no cross connections between finished product water lines and any other pipelines.
- 6.2.3 Fillers shall have the inlet so designed as to prevent the entrance of condensation. Filling valves shall be equipped with a condensation diverting apron.

### 6.3 **Containers**

- 6.3.1 Packaging processes and materials shall not transmit contaminants or objectionable substances to the bottled water;
- 6.3.2 Containers and closures for bottled water shall be in compliance with those requirements contained in Food and Drugs 21 CFR;
- 6.3.3 Only sanitary, nontoxic lubricants shall be used on container contact surfaces;
- 6.3.4 Bottles shall be provided with a tamper-evident seal or cap;
- 6.3.5 Screw, snap or crown caps shall be single use, and shall be sanitized.
- 6.3.6 Each container of bottled drinking water shall be identified by a product code, identifying a particular batch or segment of a continuous production run, and the day produced.
- 6.3.7 The plant shall record and maintain the following information:
  - (a) product
  - (b) volume produced
  - (c) date
  - (d) lot code
  - (e) distribution

6.4 **Recall Plan**

The plant shall have on file an approved, written recall plan, which shall detail procedures for recall of any particular batch as identified in the above section.

Section 7.0 ***Sanitation and Maintenance***

7.1 Buildings and other physical facilities of the plant shall be kept in good repair, as indicated in Section 5.0.

7.2 **Equipment.**

All tanks, pipelines and equipment used to store, handle and transport water shall be inspected, maintained, cleaned and sanitized according to the following requirements:

7.2.1 Storage tanks shall be:

- (a) Inspected for cleanliness on a monthly basis and shall be kept free of scale, evidence of oxidation, and residue.
- (b) Cleaned on a monthly basis by sanitizing with one of the following and flushing with product water:
  - (i) Chlorinated water solution of 200 ppm for 5 minutes minimum.
  - (ii) Chlorinated water solution by spraying 200 ppm 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.

(iv) 0.1 ppm ozonated water solution for not less than ten minutes contact time.

7.2.2 Product water pipelines shall be:

- (a) Kept free of scale, evidence of oxidation, and residue.
- (b) Cleaned on a daily basis by sanitizing with chlorine water of 200 ppm for 5 minutes, followed by product water flushing, or continuous recirculation of at least 0.1 ppm ozonated water.

7.2.3 **Product Equipment**

- (a) Cappers shall be sanitized on a daily basis.
- (b) Hoppers shall be kept covered, free of residue and contact surfaces shall be sanitized on a daily basis.
- (c) 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.
- (d) Bottle washing equipment shall be checked daily to assure proper timing and adequate washing of bottles;
- (e) Fillers shall be kept free from 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.

7.2.4 **Lubricants**

All lubricants used in equipment for the purpose of processing/manufacturing bottled water shall be USDA/FDA approved.

7.2.5 **Dedicated Equipment**

As defined in Section 1.8 of these regulations shall be used in processing and manufacturing of bottled water.

7.3 **Personnel:**

- (a) Employees shall wear clean outer garments for any phase of product water processing.
- (b) Every worker shall wash his/her hands and forearms with soap and warm water and thoroughly rinse them in clean water, before beginning work, and/or after any interruption in work activity.
- (c) No person shall knowingly be permitted to work in a bottled water plant in any capacity who is affected by a communicable disease or other abnormal source of microbiological contamination.
- (d) No activities that may cause contamination shall be permitted in the product processing area.

**Section 8.0 *Sanitizing Bottles and Caps***

- 8.1 Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:
- 8.1.1 Steam in enclosed system: At least 170o F for at least 15 minutes or at least 200o F for at least 5 minutes
  - 8.1.2 Hot water in enclosed system: At least 170o F for at least 15 minutes or at least 200o F for at least 5 minutes.
  - 8.1.3 Chemical sanitizers shall be equivalent in bactericidal action to a 2 minute exposure of 50 parts per million of available chlorine at 57o F when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at 57o F or its equivalent in bactericidal action.
  - 8.1.4 0.1 part per million ozonated water solution in an enclosed system for at least 5 minutes.
  - 8.1.5 When containers are sanitized using a substance other than one provided for in Appendix 2, such substance shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in Section 8.1.3.
  - 8.1.6 Other methods equally protective of public health as the above, when approved by the Director, may be used.
  - 8.1.7 Single-use bottles or containers, which are free of all bacteria, dust, or other contamination, need not comply with the above sanitizing requirement prior to filling.
  - 8.1.8 Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

**Section 9.0 *Labeling***

- 9.1 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 with other printed matter on the label, cap or container.

9.1.1 **Contents of Label.** \ Each label shall indicate:

- (a) Type of Source Water:
  - (i) Water coming from springs may be labeled "Spring Water" or "Natural Spring Water".
  - (ii) Artesian or pumped water taken from the ground, from drilled wells may be labeled "Well Water", "Artesian Water", or "Natural Water".
  - (iii) (a) For water containing carbon dioxide (CO<sub>2</sub>) that emerges from the source and is bottled directly with its entrapped gas or from which the gas is mechanically separated and later reintroduced at a level not higher than naturally occurring in the water may be labeled "Naturally Carbonated" or "Naturally Sparkling".  
(b) Bottled water which contains CO<sub>2</sub> other than that naturally occurring in the source of the product shall be labeled "Carbonated", "Carbonation Added" or "Sparkling".
  - (iv) (a) Mineral water may be labeled "Mineral Water" or "Natural Mineral Water".  
(b) Bottled water to which minerals are added shall be labeled so as to disclose that minerals are added, and may not be labeled "Natural Mineral Water".
  - (v) For a municipal water supply source, the name of the municipal supply must be stated.
- (b) Other Information
  - (i) For bottled waters identified on the label as being distilled, the type of source water does not need to be indicated.
  - (ii) Purified water shall be labeled "Purified Water" and the method of preparation shall be stated on the label except that purified water produced by distillation may be labeled as "Distilled Water".
  - (iii) Supplemental printed information and graphics concerning recognized uses of the water may appear on the label but shall not imply properties of the product or preparation methods which are not factual.
  - (iv) Address and location of the bottling facility or corporate offices.
  - (v) Net contents and/or capacity of the container.
  - (vi) Location of water source must be stated.

9.1.2 **Production Code:** Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

- 9.1.3 **Sodium Labeling:** Certain descriptive terms about the quantitative sodium content of bottled water may be used on the label, provided such statements indicate the number of milligrams of sodium per measured volume of bottled water.
- 9.1.4 **Additional Label Statements:** Whenever any term such as "no fluorides", "no chlorides", "no bromides", etc. is used in labeling, quantitative information shall be provided, which includes mg. per liter or mg. per measured serving. All label statements are subject to review and approval by the Director.

Section 10.0 ***Sampling, Methods Record Keeping and Reporting.***

10.1 Bottled waters must be routinely sampled and analyzed for physical, chemical, radiological and bacteriological quality. The results of these analysis must be recorded and filed at the plant and shall be available to the Director.

10.1.1 **Sampling Requirements:**

- (a) Bottled water shall be sampled at the minimum frequency and analyzed for the water quality parameters outlined in APPENDIX I, table I, BOTTLED WATER SAMPLING REQUIREMENTS.
- (b) When necessary, more frequent sampling or additional monitoring may be required by the director.

10.1.2 **Sampling Methods and Analyses:**

- (a) Source Water samples shall be taken from each approved source.
- (b) Product water (finished product) 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 product.
- (c) All required product water quality analyses must be performed by an approved laboratory. Each laboratory must submit evidence that said laboratory is approved according to the definition in section 1.1 of these regulations.
- (d) All required source water quality analyses must be performed by a laboratory meeting either domestic approval or foreign approval by the appropriate government agency for source water analysis.
- (e) Analyses shall be conducted in accordance with the analytical requirements for drinking water set forth in Standard Methods for the Examination of Water and Wastewater, current edition, and/or applicable procedures acceptable to the Director.

10.1.3 **Container Sampling:**

- (a) Containers and closures shall be inspected to ascertain that they are free from contamination.
- (b) At least once every three months, a bacteriological swab and/or rinse count

should be made from at least four containers and closures selected just prior to 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 bacteriological tests shall be in conformity with those approved by the Director. Tests shall be performed by qualified plant personnel or an approved laboratory.

#### 10.1.4 **Record Retention and Reports:**

- (a) In State Bottlers:
  - (i) Records shall be kept of all inspections, cleaning and sanitizing operations and bottling production. Records of all bacteriological and chemical testing must also be maintained by owners and operators of bottled and bulk water facilities used for bottling and shall be available to the Director for the most recent two year period.
  - (ii) Plants shall also retain, on file at the plant, current certificates or notification of approval by the Director.
  - (iii) All required documents shall be available for official review by the Director at reasonable times.
  - (iv) All inspection and chemical and microbiological test results shall be available for not less than 2 years.
- (b) Out of State Bottlers: (Including Imported Bottled Water) must submit the following annually:
  - (i) Most recent inspection report of cleaning and sanitizing operations and bottling production performed by the government agency having jurisdiction over said bottler.
  - (ii) Current certificate of approval from appropriate health agency, and
  - (iii) All of the most recent chemical & microbiological test results.
  - (iv) All records and inspection reports shall be available for not less than 2 years.

### Section 11.0 ***Bulk Water***

Tank trucks, loading and unloading facilities, and other equipment used to transport bulk water for bottled water purposes shall be maintained clean and sanitary conditions at all times. Tanks previously used to transport milk or juice products, toxic materials, petroleum products, or other deleterious substances shall not be used to haul drinking water.

11.1.1 **Sources:** All sources of water for bulk water shipment must be approved by the Director and must meet the requirements outlined in Section 2.

11.1.2 **Storage Tanks:** All source water storage facilities must be maintained in a clean

and sanitary condition at all times and must meet the requirements outlined in Sections 6 and 7.

11.1.3 **Bulk Transport and Transfer Procedure:**

(a) **Sanitation:**

- (1) Prior to filling, tank interior shall be cleaned, flushed with potable water, sanitized with not less than 100 ppm chlorine water solution for a contact period of not less than 20 minutes, and rinsed with potable water.
- (2) All hoses, connections, and fittings shall be sanitized with a concentrated solution of chlorine (3 oz. of 5 1/4% household bleach to 2 gallons of water) by brushing solution on all exposed parts.
- (3) The cover shall not be opened after sanitizing.

(b) **Fluid Transfer:**

- (1) Tank trucks or tank trailers may be filled through the fitting on the inner dome cover when the rear pipe cannot be used.
- (2) Water quality in the tank, after 20-30 gallons have been delivered into the tank, shall be checked as follows:
  - (a) Stop filling.
  - (b) Have discharge valve opened.
  - (c) Inspect water as it discharges. If water has unpleasant odor and/or looks dirty, it shall be rejected for use, and the tank shall be resanitized per sections 11.1.3a.
- (3) When these checks indicate satisfactory water quality proceed to fill the tank.
- (4) The dome cover shall be closed and sealed after filling to volume desired.
- (5) The tank discharge valve cover shall be closed and sealed after filling.
- (6) If used a fill connection shall be constructed in a manner to prevent contamination and shall be capped at all times when not in use.

11.1.4 **Sampling:**

- (a) Analysis of the samples must be performed for the plant by an approved commercial laboratory as outlined in Section 10.
- (b) When deemed necessary by the Director, sampling of water from Bulk Water System (i.e. tank truck, water buffalo, storage tank, transfer line, etc.) shall be conducted and analyzed.

11.1.5 **Records:**

- (a) Shall be maintained and include the number of gallons delivered daily, cleansing and sanitizing methods used for tank truck and tank trailer interiors,

risers, connections, hoses, etc.

- (b) Such records shall include date, time and location of delivery, concentration of sanitizing solution, time of contact when applicable, and water quality analysis results as legal evidence of compliance with public health practices and standards.

PART III      **PERMITS**

Section 12.0    *Permits/Revocation*

- 12.1    Bottlers' permits required for manufacture or sale. It shall be unlawful for any person, firm or corporation to manufacture or bottle for sale, or to sell or offer for sale any carbonated or nonalcoholic beverage, soda water, fruit juice, syrup, mineral or spring water either plain or carbonated, or any other soft drink, so-called, without a permit from the Department of Health. No carbonated or nonalcoholic beverage, soda water, fruit juice, syrup, mineral or spring water either plain or carbonated, or any other soft drink, so-called, which has been manufactured outside of this state shall be sold or offered for sale within this state unless the person, firm or corporation manufacturing or bottling the same for sale shall hold a permit so to do from the Department of Health. Said permit shall be known as a "Bottlers' Permit" and the person, firm or corporation receiving said permit shall be known as the "Bottler".
- 12.2    The provisions of section 12.1 shall not apply to dealers at retail who purchase from the bottler of any carbonated or nonalcoholic beverage, soda water, fruit juice, bottled drinking water either plain or carbonated, or any other soft drink, so-called.
- ~~12.2~~    12.3    Issuance and Renewal of Permits - Fee - Posting - Exempt Cider. Blank forms of application for permits shall be furnished by the said department without cost. The fee for such permit shall be ~~three hundred and fifty dollars (\$350.00)~~ as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.* All permits shall expire on December thirty-first of the year in which they are issued. Application for renewal of permits must be made on or before the first day of December of each and every year. All permits granted hereunder shall be posted in a conspicuous place on the premises of the bottler so that they may readily be seen by any person inspecting the premises;
- ~~12.3~~    12.4    Suspension or Revocation of Permits. Permits granted hereunder may be suspended or revoked by the Department of Health for violation of any provision of this chapter or the regulations pursuant thereto of Chapter 21-23 or Chapter 21-31 of Rhode Island General Laws of 1956 as amended.

PART IV      ***VARIANCE PROCEDURE/VIOLATIONS/PRACTICES AND PROCEDURES/ SEVERABILITY***

Section 13.0    ***Variance Procedure***

- 13.1    The Department may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case, if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such variance will not be contrary to the public interest, public health and/or health and safety of the public.
  
- 13.2    A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made.
  - 13.2.1    Upon the filing of each request for variance with the Department and within thirty (30) days thereafter, the Department shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the applicant appeals the denial.

Section 14.0    ***Violations***

- 14.1    Any person who violates the statutory provisions and the regulations herein shall be subject to the sanctions of Section 23-16.2 of the General Laws of Rhode Island, 1956, as amended.

Section 15.0    ***Rules Governing Practices and Procedures***

- 15.1    All hearings and reviews required under the provisions of the rules and regulations herein shall be held in accordance with the rules and regulations promulgated by the Rhode Island Department of Health, entitled: "Rules and Regulations Governing the Practices and Procedures Before the Rhode Island Department of Health (R42-35-PP).

Section 16.0    ***Severability***

- 16.1    If any provision of these rules and regulations or the application thereof to any individual, facility or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

**APPENDIX I**  
**BOTTLED WATER SAMPLING REQUIREMENTS**  
**AND STANDARD OF QUALITY**

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**MICROBIOLOGICAL**

- (1) Coliform Count:
    - (a) Standard - less than one colony per 100 milliliters (ml), or absence of total coliforms in a sample.
    - (b) Frequency of samples:
      - (1) Public water supply
        - a. source water - one sample every three months.
        - b. finished product - minimum one sample per week.
      - (2) Private water supply
        - a. source water - one sample per week.
        - b. finished product - minimum one sample per week.
  - (2) Standard Plate Count for Containers and closures:
    - (a) Swab or Rinse Count Method [21 CFR, Sect. 129.80 (f)]
    - (b) Standard - sample(s) shall be free of coliform organisms.
    - (c) Frequency of samples:
      - (1) minimum of four containers every three months.
- 

**PHYSICAL**

- (1) Turbidity:
  - (a) Standard - shall not exceed five units.
  - (b) Frequency of samples:
    - (1) source water - one sample per year.
    - (2) finished product - one sample per year.
- (2) Color:
  - (a) Standard - shall not exceed 15 units.
  - (b) Frequency of samples:
    - (1) source water - one sample per year.
    - (2) finished product - one sample per year.
- (3) Odor:
  - (a) Standard - shall not exceed threshold odor No. 3.
  - (b) Frequency of Samples:
    - (1) source water - one sample per year
    - (2) finished product - one sample per year.

**APPENDIX I (cont.)**

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**RADIOLOGICAL:**

- (1) Gross Alpha Particle Activity:
    - (a) Including Radium 226 but excluding Radon & Uranium.
    - (b) Standard - shall not exceed 15 picoCuries/liter (pCi/l).
    - (c) Frequency of Samples:
      - (1) source water - one sample every three years.
      - (2) finished product - one sample every three years.
    - (d) If gross alpha particle activity is 5 pCi/l or less, there is not a need to analyze for Radium 226 and Radium 228. If the gross alpha particle activity exceeds 5 pCi/l, the sample must be analyzed for Radium 226. If the concentration of Radium 226 exceeds 3 pCi/l, the concentration of Radium 228 shall be determined.
  - (2) Combined Radium 226 and Radium 228:
    - (a) Standard - shall not exceed 5 picoCuries per liter.
    - (b) Frequency of Samples:
      - (1) source water - one sample every three years.
      - (2) finished product - one sample every three years.
  - (3) Manmade Beta Particle Activity and Photon Emitters:
    - (a) Standard - shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of intake of 2 liters of water per day.
    - (b) Compliance may be assumed if the average annual concentration of gross beta particle activity is less than 50 pCi/l and the average annual concentration of tritium and strontium 90 are less than 20,000 pCi/l and 8 pCi/l respectively and the sum of their annual dose not to exceed 4 millirems per year.
    - (c) Frequency of Samples:
      - (1) source water - one sample every three years.
      - (2) finished product - one sample every three years.
- 

**INORGANIC CHEMICALS:**

- (1) Frequency of Sampling:
  - (a) Samples of source water and finished product are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for the following chemicals:

**APPENDIX I (cont.)****INORGANIC CHEMICALS (cont):**

| <u>Chemical Name</u>         | <u>Standard (mg/l)</u> |
|------------------------------|------------------------|
| 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)                 | 4.0 (source water)     |
| Iron (Fe)                    | 0.3                    |
| Lead (Pb)                    | 0.05                   |
| Manganese (Mn)               | 0.05                   |
| Mercury (Hg)                 | 0.002                  |
| Nitrate (NO <sub>3</sub> )   | 10.0                   |
| Nitrate/Nitrite, Total       | 10.0                   |
| Nitrite (NO <sub>2</sub> )   | 1.0                    |
| Phenols                      | 0.001                  |
| Selenium (Se)                | 0.01                   |
| Silver (Ag)                  | 0.05                   |
| Sodium (Na)                  |                        |
| Sulfate (SO <sub>4</sub> )   | 250.0                  |
| Total Dissolved Solids (TDS) | 500.0*                 |
| Zinc (Zn)                    | 5.0                    |

\* mineral water shall be greater than 500.0 mg/l.

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**ORGANIC CHEMICALS****(1) Frequency of Sampling:**

- (a) Samples of source water and finished product are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for the following chemicals:

| <u>Chemical Name</u>  | <u>Standard (mg/l)</u> |
|---|------------------------|
| Total Trihalomethanes (TTHM):<br>(Bromoform, Bromodichloromethane,<br>Chlorodibromomethane, Chloroform) | 0.100                  |
| Pesticides:   |                        |
| Endrin  | 0.0002                 |
| Lindane   | 0.004                  |

**APPENDIX I (cont.)****ORGANIC CHEMICALS (cont.):**

| <u>Chemical Name</u>  | <u>Standard (mg/l)</u> |
|---|------------------------|
| Methoxychlor  | 0.1                    |
| Toxaphene   | 0.005                  |
| 2,4-D   | 0.1                    |
| 2,4,5-TP Silvex   | 0.01                   |
| Total Aldicarb<br>(Aldicarb, Aldicarb Sulfone,<br>Aldicarb Sulfoxide) | 0.01                   |
| Volatile Organic Chemicals:   |                        |
| Benzene   | 0.005                  |
| Carbon Tetrachloride  | 0.005                  |
| 1,2-Dichloroethane  | 0.005                  |
| Trichloroethylene   | 0.005                  |
| para-dichlorobenzene  | 0.075                  |
| 1,1-dichloroethylene  | 0.007                  |
| 1,1,1-trichloroethane   | 0.200                  |
| Vinyl Chloride  | 0.002                  |
| Unregulated Contaminants:   |                        |
| Trans-1,2-Dichloroethylene  |                        |
| Chlorobenzene   |                        |
| m-Dichlorobenzene   |                        |
| Dichloromethane   |                        |
| cis-1,2-Dichloroethylene  |                        |
| o-Dichlorobenzene   |                        |
| Dibromoethane   |                        |
| 1,1-Dichloropropene   |                        |
| Tetrachloroethylene   |                        |
| Toluene   |                        |
| p-Xylene  |                        |
| o-Xylene  |                        |
| m-Xylene  |                        |
| 1,1-Dichloroethane  |                        |
| 1,2-Dichloropropane   |                        |
| 1,1,2,2-Tetrachloroethane   |                        |
| Ethylbenzene  |                        |
| 1,3-Dichloropropane   |                        |

**APPENDIX I (cont.)****ORGANIC CHEMICALS (cont.):**

| <u>Chemical Name</u>               | <u>Standard (mg/l)</u> |
|------------------------------------|------------------------|
| Styrene                            |                        |
| Chloromethane                      |                        |
| Bromomethane                       |                        |
| Bromochloromethane                 |                        |
| 1,2,3-Trichloropropane             |                        |
| 1,1,1,2-Tetrachloroethane          |                        |
| Chloroethane                       |                        |
| 1,1,2-Trichloroethane              |                        |
| 2,2-Dichloropropane                |                        |
| Chemical                           |                        |
| o-Chlorotoluene                    |                        |
| p-Chlorotoluene                    |                        |
| Bromobenzene                       |                        |
| 1,3-Dichloropropene                |                        |
| Ethylene dibromide (EDB)           |                        |
| 1,2-Dibromo-3-chloropropane (DBCP) |                        |
| 1,2,4-Trimethylbenzene             |                        |
| 1,2,4-Trichlorobenzene             |                        |
| 1,2,3-Trichlorobenzene             |                        |
| n-Propylbenzene                    |                        |
| n-Butylbenzene                     |                        |
| Naphthalene                        |                        |
| Hexachlorobutadiene                |                        |
| 1,3,5-Trimethylbenzene             |                        |
| p-Isopropyltoluene                 |                        |
| Isopropylbenzene                   |                        |
| Tert-butylbenzene                  |                        |
| Sec-butylbenzene                   |                        |
| Fluorotrichloromethane             |                        |
| Dichlorodifluoromethane            |                        |

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## APPENDIX II SANITIZING SOLUTIONS

Source: 21 CFR (4-1-87 Edition)

### Section 178.1010 Sanitizing Solutions.

Sanitizing solutions may be safely used on food-processing equipment and utensils, and on other food-contact articles as specified in this section, within the following prescribed conditions:

- (a) Such sanitizing solutions are used, followed by adequate draining, before contact with food.
- (b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval.
  - (1) An aqueous solution containing potassium, sodium, or calcium hypochlorite, with or without the bromides of potassium, sodium, or calcium.
  - (2) An aqueous solution containing dichloroisocyanuric acid, trichloroisocyanuric acid, or the sodium or potassium salts of these acids, with or without the bromides of potassium, sodium, or calcium.
  - (3) An aqueous solution containing potassium iodide, sodium p-toluenesulfonchloroamide, and sodium lauryl sulfate.
  - (4) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a cloudpoint of 90°-100° C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and ethylene glycol monobutyl ether. Additionally, the aqueous solution may contain diethylene glycol monoethyl ether as an optional ingredient.
  - (5) An aqueous solution containing elemental iodine, hydriodic acid, a-(p-nonylphenyl)-omega-hydroxypoly-(oxyethylene) (complying with the identity prescribed in Section 178.3400(c) and having a maximum average molecular weight of 748 and/or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900). Additionally, the aqueous solution may contain isopropyl alcohol as an optional ingredient.
  - (6) An aqueous solution containing elemental iodine, sodium iodide, sodium dioctylsulfosuccinate, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900).
  - (7) An aqueous solution containing dodecylbenzenesulfonic acid and either isopropyl alcohol or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.
  - (8) An aqueous solution containing elemental iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a minimum average molecular weight of 2,400 and a-lauroyl-omega-hydroxypoly (oxyethylene) with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. In addition to use on food processing equipment and utensils, this solution may be used on beverage containers, including milk containers or equipment. Rinse water treated with this solution can be recirculated as a preliminary rinse. It is not to be used as final rinse.

## APPENDIX II (cont.)

- (9) An aqueous solution containing n-alkyl (C<sub>12</sub>-C<sub>18</sub>) benzyldimethylammonium chloride compounds having average molecular weights of 351 to 380. The alkyl groups consist principally of groups with 12 to 16 carbon atoms and contain not more than 1 percent each of groups with 8 and 10 carbon atoms. Additionally, the aqueous solution may contain either ethyl alcohol or isopropyl alcohol as an optional ingredient.
- (10) An aqueous solution containing trichloromelamine and either sodium lauryl sulfate or dodecyl-benzenesulfonic acid. In addition to use on food-processing equipment and utensils and other food-contact articles, this solution may be used on beverage containers except milk containers or equipment.
- (11) An aqueous solution containing equal amounts of n-alkyl (C<sub>12</sub>-C<sub>18</sub>) benzyl dimethyl ammonium chloride and n-alkyl (C<sub>12</sub>-C<sub>18</sub>) dimethyl ethylbenzyl ammonium chloride (having an average molecular weight of 384). In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.
- (12) An aqueous solution containing the sodium salt of sulfonated oleic acid, polyoxyethylene-polyoxypropylene block polymers (having an average molecular weight of 2,000 and 27 to 31 moles of polyoxypropylene). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk. All equipment, utensils, glass bottles, and other glass containers treated with this sanitizing solution shall have a drainage period of 15 minutes prior to use in contact with food.
- (13) An aqueous solution containing elemental iodine and alkyl (C<sub>12</sub>-C<sub>15</sub>) monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 70°-77°C in 1 percent aqueous solution and an average molecular weight of 807.
- (14) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud-point of 90°-100°C in 0.5 percent aqueous solution and an average molecular weight of 3,300 and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,000).
- (15) An aqueous solution containing lithium hypochlorite.
- (16) An aqueous solution containing equal amounts of n-alkyl (C<sub>12</sub>-C<sub>18</sub>) benzyl dimethyl ammonium chloride and n-alkyl (C<sub>12</sub>-C<sub>14</sub>) dimethyl ethylbenzyl ammonium chloride (having average molecular weights of 377 to 384), with the optional adjuvant substances tetrasodium ethylenediamin- tetraacetate and/or alpha-(p-nonylphenol)-omega-hydroxy poly (oxyethylene) having an average poly-(oxyethylene) content of 11 moles. Alpha-hydro-omega-hydroxypoly-(oxyethylene) poly(oxypropylene) (15 to 18 mole minimum) poly (oxyethylene) block copolymer, having a minimum molecular weight of 1,900 (CAS Registry No. 9003-11-6) may be used in lieu of alpha-(p-nonylphenol)-omega-hydroxy- poly(oxyethylene) having an average poly(oxyethylene) content of 11 moles. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

## APPENDIX II (cont.)

- (17) An aqueous solution containing di-n-alkyl(C<sub>8</sub>-C<sub>10</sub>)dimethyl ammonium chlorides having average molecular weights of 332-361 and either ethyl alcohol or isopropyl alcohol. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.
- (18) An aqueous solution containing n-alkyl(C<sub>12</sub>-C<sub>18</sub>) benzyldimethylammonium chloride, sodium metaborate, alpha-terpineol and alpha-[p-(1,1,2,3-tetramethylbutyl)phenyl] - omega-hydroxy-poly (oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide.
- (19) An aqueous solution containing sodium dichloroisocyanurate and tetrasodium ethylenediaminetetraacetate. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.
- (20) An aqueous solution containing ortho-phenylphenol, ortho-benzyl-para-chlorophenol, para-tertiaryamylphenol, sodium -alpha-alkyl(C<sub>12</sub>-C<sub>15</sub>)-omega-hydroxypoly (oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole, potassium salts of coconut oil fatty acids, and isopropyl alcohol or hexylene glycol.
- (21) An aqueous solution containing sodium dodecylbenzenesulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.
- (22) An aqueous solution containing (1) di-n-alkyl(C<sub>8</sub>-C<sub>10</sub>) dimethylammonium chloride compounds having average molecular weights of 332-361 (2) n-alkyl (C<sub>12</sub>-C<sub>18</sub>) benzyldimethylammonium chloride compounds having average molecular weights of 351-380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without not over 1 percent each of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.
- (23) An aqueous solution containing n-alkyl (C<sub>12</sub>-C<sub>16</sub>) benzyl-dimethylammonium chloride and didecyldimethylammonium chloride.
- (24) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), alpha-[p-(1,1,3,3-tetramethylbutyl)-phenyl]-omega-hydroxypoly-(oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide, and alpha-alkyl(C<sub>12</sub>-C<sub>15</sub>)-omega-hydroxy[poly(oxyethylene) poly(oxypropylene)] (having an average molecular weight of 965).
- (25) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), potassium iodide (CAS Reg. No. 7681-11-0), and isopropanol (CAS Reg. No. 67-63-0). In addition to use on food processing equipment and utensils, this solution may be used on beverage containers, including milk containers and equipment and on food-contact surfaces in public eating places.
- (26) [Reserved]
- (27) An aqueous solution containing decanoic acid (CAS Reg. No. 334-48-5), octanoic acid (CAS Reg. No. 124-07-2), and sodium 1-octanesulfonate (CAS) Reg. No. 5324-84-5). Additionally, the aqueous solution may contain isopropyl alcohol (CAS Reg. No.67-63-0) as an optional ingredient.

## APPENDIX II (cont.)

- (28) An aqueous solution containing sulfonated 9-octadecenoic acid (CAS Reg. No. 68988-76-1) and sodium xylenesulfonate (CAS Reg. No. 1300-72-7).
  - (29) An aqueous solution containing dodecyldiphenyloxidedisulfonic acid (CAS Reg. No. 30260-73-2), sulfonated tall oil fatty acid (CAS Reg. No. 68309-27-3), and neo-decanoic acid (CAS Reg. No. 26896-20-8). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.
  - (30) An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722-84-1), peracetic acid (CAS Reg. No. 79-21-0), acetic acid (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4).
  - (31) An aqueous solution containing elemental iodine, alpha-alkyl(C<sub>10</sub>-C<sub>14</sub>)-omega-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and alpha-alkyl(C<sub>12</sub>-C<sub>18</sub>)-omega-hydroxypoly(oxyethylene) poly-(oxypropylene) of average molecular weight between 950 and 1,120. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.
  - (32) An aqueous solution containing (i) di-n-alkyl(C<sub>8</sub>-C<sub>10</sub>)-dimethylammonium chloride compounds having average molecular weights of 332 to 361, (ii) n-alkyl(C<sub>12</sub>-C<sub>18</sub>)-benzyltrimethylammonium chloride compounds having average molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of groups with 8 and 10, (iii) ethyl alcohol, and (iv) alpha-(p-nonyl-phenyl)-omega-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of p-nonylphenol with 9 to 12 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.
  - (33) An aqueous solution containing (i) di-n-alkyl-(C<sub>8</sub>-C<sub>10</sub>)-dimethylammonium chloride compounds having average molecular weights of 332 to 361; (ii) n-alkyl(C<sub>12</sub>-C<sub>18</sub>)-benzyltrimethylammonium chloride compounds having molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of the groups with 8 to 10; and (iii) tetrasodium ethylenediamine tetraacetate. Additionally, the aqueous solution contains either alpha-(p-nonylphenyl)-omega-hydroxypoly-(oxyethylene) or alpha-alkyl(C<sub>11</sub>-C<sub>15</sub>)-omega-hydroxypoly-(oxyethylene), each produced with 9 to 13 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.
- (c) The solutions identified in paragraph (b) of this section will not exceed the following concentrations:
- (1) Solutions identified in paragraph (b)(1) of this section will provide not more than 200 parts per million of available halogen determined as available chlorine.
  - (2) Solutions identified in paragraph (b)(2) of this section will provide not more than 100 parts per million of available halogen determined as available chlorine
  - (3) Solution identified in paragraph (b)(3) of this section will provide not more than 25 parts per million of titratable iodine. The solutions will contain the components potassium iodide, sodium p-toluenesulfonchloramide and sodium lauryl sulfate at a level not in

excess of the minimum required to produce their intended functional effect.

## APPENDIX II (cont.)

- (4) Solutions identified in paragraph (b)(4), (5), (6), (8), (13), and (14) of this section will contain iodine to provide not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.
- (5) Solutions identified in paragraph (b)(7) of this section will provide not more than 400 parts per million dodecylbenzenesulfonic acid and not more than 80 parts per million of polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800) or not more than 40 parts per million of isopropyl alcohol.
- (6) Solutions identified in paragraph (b)(9) of this section shall provide when ready to use no more than 200 parts per million of the active quarternary compound.
- (7) Solutions identified in paragraph (b)(10) of this section shall provide not more than sufficient trichloromelamine to produce 200 parts per million of available chlorine and either sodium lauryl sulfate at a level not in excess of the minimum required to produce its intended functional effect or not more than 400 parts per million of dodecylbenzenesulfonic acid.
- (8) Solutions identified in paragraph (b)(11) of this section shall provide, when ready to use, not more than 200 parts per million of active quaternary compound.
- (9) The solution identified in paragraph (b)(12) of this section shall provide not more than 200 parts per million of sulfonated oleic acid, sodium salt.
- (10) Solutions identified in paragraph (b)(15) of this section will provide not more than 200 parts per million of available chlorine and not more than 30 ppm lithium.
- (11) Solutions identified in paragraph (b)(16) of this section shall provide not more than 200 parts per million of active quaternary compound.
- (12) Solutions identified in paragraph (b)(17) of this section shall provide, when ready to use, a level of 150 parts per million of the active quarternary compound.
- (13) Solutions identified in paragraph (b)(18) of this section shall provide not more than 200 parts per million of active quaternary compound and not more than 66 parts per million of alpha[p-(1,1,3,3-tetramethylbutyl) phenyl]-omega-hydroxypoly (oxyethylene).
- (14) Solutions identified in paragraph (b)(19) of this section shall provide, when ready to use, a level of 100 parts per million of available chlorine.
- (15) Solutions identified in paragraph (b)(20) of this section are for single use applications only and shall provide, when ready to use, a level of 800 parts per million of total active phenols consisting of 400 parts per million ortho-phenylphenol, 320 parts per million ortho-benzyl-para-chlorophenol and 80 parts per million para-tertiaryamylphenol.
- (16) Solution identified in paragraph (b)(21) of this section shall provide not more than 430 parts per million and not less than 25 parts per million of sodium dodecylbenzenesulfonate.
- (17) Solutions identified in paragraph (b)(22) of this section shall provide when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compound.
- (18) Solutions identified in paragraph (b)(23) of this section shall provide at least 150 parts per million and not more than 200 parts per million of the active quaternary compound.

- (19) Solutions identified in paragraphs (b)(24) and (b)(25) of this section shall provide at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine shall not be in excess of the minimum amounts required to accomplish the intended technical effect.
- (20)-(21) [Reserved]
- (22) Solutions identified in paragraph (b)(27) of this section shall provide, when ready to use, at least 109 parts per million and not more than 218 parts per million of total active fatty acids and at least 156 parts per million and not more than 312 parts per million of the sodium 1-octanesulfonate.
- (23) Solutions identified in paragraph (b)(28) of this section shall provide, when ready to use, at least 156 parts per million and not more than 312 parts per million of sulfonated 9-octadecenoic acid, at least 31 parts per million and not more than 62 parts per million of sodium xylenesulfonate.
- (24) Solutions identified in paragraph (b)(29) of this section will provide at least 237 parts per million and not more than 474 parts per million dodecyldiphenyloxidedisulfonic acid, at least 33 parts per million and not more than 66 parts per million sulfonated tall oil fatty acid, and at least 87 parts per million and not more than 174 parts per million neodecanoic acid.
- (25) Solutions identified in paragraph (b)(30) of this section shall provide, when ready to use, not less than 550 parts per million and not more than 1,100 parts per million hydrogen peroxide, not less than 100 parts per million and not more than 200 parts per million peracetic acid, not less than 150 parts per million and not more than 300 parts per million acetic acid, and not less than 15 parts per million and not more than 30 parts per million 1-hydroxyethylidene-1,1-diphosphonic acid.
- (26) The solution identified in paragraph (b)(31) of this section shall provide, when ready to use, at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.
- (27) Solutions identified in paragraph (b)(32) of this section shall provide, when ready to use, at least 150 parts per million and no more than 400 parts per million of active quarternary compounds in solutions containing no more than 600 parts per million water hardness. The adjuvants used with the quarternary compounds will not exceed the amounts required to accomplish the intended technical effect.
- (28) Solutions identified in paragraph (b)(33) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compounds. The adjuvants used with the quaternary compounds shall not exceed the amounts required to accomplish the intended technical effect. Tetrasodium ethylenediamine tetraacetate shall be added at a minimum level of 60 parts per million. Use of these sanitizing solutions shall be limited to conditions of water hardness not in excess of 300 parts per million.
- (d) Sanitizing agents for use in accordance with this section will bear labeling meeting the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

## ***REFERENCES***

1. Standard Methods for the Examination of Water and Wastewater, current edition.
2. Rules and Regulations Pertaining to Public Drinking Water (R46-13-DWQ) Rhode Island Department of Health.

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*Thursday, 09 August 2012*