

Regulation 61-32

Soft Drink and Water Bottling Plants

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SECTION I. PURPOSE

This regulation sets forth minimum health standards, procedures and practices to ensure that soft drinks and bottled waters are manufactured in South Carolina in a safe and wholesome manner.

SECTION II. SCOPE

This regulation shall apply to all persons in South Carolina who manufacture or bottle soft drinks and bottled waters sold for human consumption in South Carolina.

SECTION III. DEFINITIONS

ADEQUATE - shall mean substantial compliance with acceptable health standards, procedures and practices.

ADULTERATED or **ADULTERATION** - the presence or addition of any harmful or unwholesome substance, article, object, or other ingredients which may dilute or lower the quality of the beverage involved or any substance which is prohibited by law or regulation in a soft drink or bottled water.

APPROVED - acceptable to the Department based on a determination as to conformance with applicable standards and good public health practice.

APPROVED LABORATORY - a laboratory approved by the Department or certified by the U.S. Environmental Protection Agency (EPA), or certified (accredited) by a third-party organization acceptable to the Department.

APPROVED SOURCE - when used in reference to a bottled water plant's product water or water used in the plant's operations, 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 of a safe and sanitary quality with or without treatment, and approved by the Department in accordance with Regulation 61-58, State Primary Drinking Water Regulations.

ARTESIAN WATER - bottled water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to the Department that the water level stands at some height above the top of the aquifer.

BOTTLED WATER - water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. It does not include those food ingredients that are declared in ingredient labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water."

BOTTLING - filling, capping, packaging or enclosing in containers.

BOTTLING PLANT - any establishment involved in the manufacturing or packaging of soft drinks and bottled waters.

BULK WATER - source water collected at an approved site remote from the bottling plant and transported to the bottling plant for further processing and bottling.

CODE OF FEDERAL REGULATION (CFR) - a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

CONTAINER - any material used for the packaging of soft drinks and bottled waters, whether of glass, plastic, metal, paper or any combination thereof.

DEMINERALIZED WATER - bottled water which is produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia and specified by the U. S. Food and Drug Administration (FDA) in 21 CFR Section 165.110.

DEIONIZED WATER - bottled water that has been produced by a process of deionization and that meets the definition of "purified water" in the United States Pharmacopoeia and specified by the FDA in 21 CFR Section 165.110.

DEPARTMENT - the South Carolina Department of Health and Environmental Control acting through its authorized representatives.

DISTILLED WATER - bottled water which has been produced by a process of distillation and meets the definition of "purified water" in the United States Pharmacopoeia and specified by FDA in 21 CFR Section 165.110.

DRINKING WATER - water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents.

EASILY CLEANABLE - surfaces that are readily accessible and made of such materials and finishes and fabricated in such a way that residue may be effectively removed by normal cleaning methods.

EMPLOYEE - any person in a bottling plant engaged in the mixing of syrups, filling of containers, or any other capacity which brings them into contact with ingredients, containers, or equipment used in the manufacturing and packaging of soft drinks and bottled waters.

EQUIPMENT - all machinery, utensils, conveyors, containers, cases, and other articles used in the manufacturing of soft drinks and bottled waters.

FOOD - raw materials and ingredients.

FOOD-CONTACT SURFACE - the surface of any object coming into direct contact with ingredients and finished products during storage and manufacture. This shall include any surface upon which the product routinely may drip, drain, or be drawn into, as part of normal processing.

GROUND WATER - water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. Ground water must not be under the direct influence of surface water.

MICROORGANISMS - mean yeast, molds, bacteria and viruses and include, but are not limited to, species having public health significance.

MINERAL WATER - bottled water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more boreholes or springs, originating from a geologically and physically protected underground water source. Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.

NATURAL WATER - bottled spring, mineral, artesian, or well water which is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation or equivalent disinfection process).

PERSON - any individual, plant operator, partnership, company, corporation, trustee, association, or a public or private entity.

PEST - any animals or insects including, but not limited to, birds, rodents, flies and larvae.

PURIFIED WATER - bottled water produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.

REMODELED - any enlarging, replacing of floors, walls or ceilings, or changing in any respect, the structure at which a soft drink or water bottling plant is housed; provided, however, this shall not apply to repainting or refinishing of floors or walls.

REVERSE OSMOSIS WATER - bottled water that is produced by a process of reverse osmosis and that meets the definition of “purified water” in the United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.

SANITIZE - to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance.

SHALL - the item or condition discussed is mandatory.

SHOULD or MAY - the item or condition discussed is preferred but not mandatory.

SOFT DRINK - any nonalcoholic flavored carbonated beverage, soda or soda water, fruit juice, fruit drink, nonalcoholic still beverage, and seltzer or club soda.

SPARKLING BOTTLED WATER - bottled water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at the emergence from the source. Manufacturers may add carbonation to previously noncarbonated bottled water products and label such water appropriately (e.g. sparkling spring water).

SPRING WATER - bottled water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must comply with the FDA standard of identity in 21 CFR 165.110.

STANDARD OF IDENTITY - the FDA Standard of Identity for bottled water as set forth in 21 CFR 165.110.

STANDARD OF QUALITY - the FDA Standards of Quality for bottled as set forth in 21 CFR 165.110.

STERILE WATER - bottled water that meets the requirements under “Sterility Tests” <71> in the current United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.

UNDESIRABLE MICROORGANISMS - those microorganisms which are considered to be of public health significance, which subject food to decomposition, which indicate that food is contaminated with filth, or which otherwise may cause food to be adulterated.

WELL WATER - bottled water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.

SECTION IV. PERSONNEL

A. DISEASE CONTROL

Any person who by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which may contribute to the reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations expected to result in such contamination, until the condition is corrected. All personnel shall be instructed to report such health conditions to their supervisors.

B. CLEANLINESS

All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. Methods for maintaining cleanliness to prevent food contamination include, but are not limited to:

1. Wearing outer garments suitable for the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
2. Maintaining adequate personal cleanliness.
3. Washing hands thoroughly (and sanitizing, if necessary, to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. Signs shall be posted reminding employees to wash their hands before returning to work.
4. Removing all insecure jewelry or other objects which might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it should be covered by material that can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
5. Maintaining gloves used in food handling in an intact, clean, and sanitary condition. These gloves should be of an impermeable material.
6. Where appropriate, wearing in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.

7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

8. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

9. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

C. EDUCATION AND TRAINING

Personnel responsible for identifying sanitation failures or food contamination should have a background in education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food protection principles, and should be informed of the danger of poor personal hygiene and unsanitary practices.

D. SUPERVISION

Responsibility for ensuring compliance by all personnel with all requirements of this section shall be clearly assigned to competent supervisory personnel.

SECTION V. GROUNDS, BUILDINGS AND FACILITIES

A. GROUNDS

The grounds around a bottling plant under the control of the operator shall be kept in such condition to protect against the contamination of its products. The methods for adequate maintenance of grounds include, but are not limited to:

1. Properly storing equipment, removing litter and waste, and cutting weeds or grass in the immediate vicinity of plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

3. Adequately draining areas that may contribute to the contamination of food by seepage, foot-borne filth, or providing a breeding place for pests.

4. Operating waste treatment and disposal systems in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

B. BUILDING CONSTRUCTION AND DESIGN

Bottling plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes and to prevent drip and condensation from fixtures, ducts and pipes from contaminating foods, food-contact surfaces or food containers. Sufficient space shall be provided for the placement of equipment and storage of materials as deemed

necessary for the proper maintenance of sanitary operations and production of safe food. Bottling plants shall meet, but not be limited to, the following:

1. REQUIRED ROOMS

(a) Whenever ingredients are mixed, a separate room (commonly called a syrup or blend room) or separate area of the filling room shall be provided for this purpose. This room or separate area of the filling room shall be used only for mixing ingredients and storage of mixed batches.

(b) A separate room shall be provided for filling and sealing containers (commonly called a filling or bottling room). This room shall contain only necessary filling, sealing, electronic inspection, coding and labeling equipment. Only the exit end of the bottle washing machine shall open into this room through a tight-fitting wall. If approved by the Department, the mixing of ingredients and storage of mixed batches can be conducted in this room.

2. FLOORS

(a) The floors of the syrup and filling rooms shall be constructed of concrete or equally impervious, easily cleanable material, and shall be kept clean, in good repair, and properly sloped to trapped drains to prevent pools of standing water after flushing. Integral coved juncture bases should be provided in these areas.

(b) The floors of storage, packaging and accessory rooms shall be easily cleanable, and be kept clean and in good repair at all times.

3. WALLS AND CEILINGS

(a) The walls and ceilings in the syrup and filling rooms shall be smooth, washable, light colored, and shall be kept clean and in good repair at all times. Lay-in ceiling tile panels may be used if they are designed to be easily removable for cleaning and replacement, as needed.

(b) The walls and ceilings of storage, packaging and accessory rooms or areas shall be of sound construction and kept clean and in good repair at all times.

4. LIGHTING

(a) Adequate lighting shall be provided in all areas of the plant. A minimum of 20 foot-candles of light should be provided in all working areas, and a minimum of 10 foot-candles in all storage areas.

(b) Adequate protection from glass breakage and falling debris shall be provided for all light bulbs and fixtures located over exposed food or unsealed containers in any step of preparation.

5. VENTILATION

(a) Adequate ventilation or control equipment shall be provided to minimize odors, vapors and moisture and to keep excessive carbon dioxide, ozone, and other processing gases, from accumulating in areas where soft drinks and bottled waters are manufactured.

(b) Pressurized ventilating systems shall have a filtered air intake.

(c) Fans and other air-moving equipment shall be located and operated in a manner minimizing the potential for contaminating food and unsealed containers.

6. DOORS AND WINDOWS

(a) All openings into the syrup and filling rooms shall be adequately protected against the entrance of dust and insects by tight-fitting, self-closing doors, closed windows, screening, air curtains, vinyl or rubber strip curtains, or by other means approved by the Department.

(b) Screens for windows, doors, skylights, transoms, intake and exhaust air ducts, and other openings into the syrup and filling rooms shall be tight-fitting and free of breaks. Screening materials shall not be less than sixteen mesh to the inch.

(c) Openings for conveyor lines into the filling room shall be as small as possible.

(d) Solid doors for the syrup and filling rooms shall be outward opening unless accompanied by self-closing, outward-opening screen doors.

C. SANITARY FACILITIES AND CONTROLS

Each bottling plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:

1. WATER SUPPLY

(a) The water supply shall be from a public water system approved by the Department.

(b) The design, operation and maintenance of water purification systems used to further treat potable water shall be approved by the Department. They shall not be operated beyond their rated capacity and shall be maintained in a clean, sanitary condition at all times. This shall include dispensed water vending machines.

(c) Potable running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of soft drinks and bottled waters, for the cleaning of equipment, utensils, and containers, and for employee sanitary facilities.

(d) Carbonated water shall be conveyed in approved stainless steel or equal food-grade piping and not in piping of galvanized iron, lead, zinc, or other deleterious materials.

(e) All water storage and cooling tanks shall be of noncorrosive material, properly covered, air vents properly filtered, clean, free from dust both inside and outside, and the inlet and outlet so arranged as to prevent contamination during filling and emptying.

D. TRANSPORTATION OF BULK WATER.

1. Bulk water shall be from a public water system approved by the Department.

2. The means and methods of transporting bulk water shall be approved by the Department. Bulk tanks, hoses, pumps and connections used for loading, transporting and unloading water shall be sanitized. Source water for transport shall be treated with an effective disinfectant approved by the Department at an approved concentration prior to being transported.

3. Tank filling and delivery hose connections shall be cleaned and sanitized on a regular basis. The tank shall be sealed at all times except when being filled, being cleaned and sanitized and when the water is being unloaded. A record of such cleaning and sanitizing shall be maintained with the vehicle and shall be available upon request by the Department. Pumps, hoses, connections and fittings shall be capped and protected from contamination when not in use. The tank manhole shall not be used as a means of filling the tank. To prevent collapse of the tank during delivery of bulk water, the manhole may be opened but shall be provided with an air filter to prevent contamination.

4. All surfaces which come into contact with water during storage prior to transport, shall be of smooth, impervious, nonabsorbent, corrosion resistant and nontoxic material such as stainless steel of the American Iron and Steel Institute 300 Series, or equally corrosion resistant, nontoxic material. All water contact surfaces shall be free of substances which may render the water hazardous to health or which may adversely affect the flavor, color, turbidity, odor, radiological, microbiological or chemical quality of the water.

5. Bulk water transport is intended to move source water from one area to another for the purpose of treatment, packaging and human consumption. Such water shall not be dispensed directly to consumers from a bulk water transport tank or indirectly through some other vending device unless otherwise approved by the Department. In case of an emergency, such as a drinking water shortage or outage, or a contaminated water supply, treated water may be dispensed directly from a properly sanitized water transport tank.

E. DISPOSAL OF WASTES.

1. All liquid wastes shall be disposed of by connection to a public sewer or as approved by the Department.

2. Rubbish, refuse, and garbage shall be so handled, stored and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces and water supplies.

F. PLUMBING.

Plumbing shall meet all applicable state and local plumbing laws, ordinances and regulations, and shall be sized, installed and maintained to:

1. Carry sufficient quantities of water to required locations throughout the bottling plant.

2. Properly convey sewage and liquid disposable waste from the bottling plant.

3. Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an unsanitary condition.

4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

5. Prevent backflow or back-siphonage from, or cross-connection between, piping systems discharging wastewater or sewage and piping systems carrying water for soft drink and bottled water manufacturing. This shall include adequate backflow and back-siphonage protection for water lines used to transport detergents, sanitizers, lubricants, etc.

G. TOILET FACILITIES.

1. Toilet facilities shall be approved by the Department, shall be adequate, conveniently located, accessible to employees at all times, and shall conform to applicable building and plumbing codes.
2. Toilet room floors shall be easily cleanable. Toilet room floors should be properly sloped to trapped drains.
3. Toilet room walls and ceilings shall be of sound construction. Toilet room walls shall be smooth and washable to at least a wainscot height.
4. Toilet rooms shall not open directly into the syrup or filling rooms.
5. Toilet room doors shall be self-closing.
6. Toilet rooms shall be adequately ventilated. Toilet room windows opened for ventilation shall be properly screened.
7. Toilet rooms shall be kept clean, in good repair and free of insects at all times.
8. Approved hand-washing signs shall be posted in each toilet room used by production employees.
9. Toilet tissue, soap, individual towels and trash receptacles shall be provided.

H. DRESSING ROOMS AND LOCKER AREAS.

1. If employees routinely change clothes within the bottling plant, rooms or areas shall be designated and used for that purpose and shall be kept clean and in good repair.
2. Adequate lockers or other suitable facilities shall be provided and used for the orderly storage of employee clothing and other belongings and shall be kept clean. Personnel lockers shall not be located in the syrup or filling rooms.

I. HAND-WASHING FACILITIES.

1. An adequate number of lavatories, convenient to toilet rooms and production areas, shall be provided.
2. Each lavatory shall be provided with hot and cold running water, soap and approved sanitary towels, or other approved hand-drying devices. If disposable towels are used, easily cleanable waste receptacles shall be conveniently located near the hand washing facilities.

J. SANITARY OPERATIONS.

1. GENERAL MAINTENANCE

Buildings, fixtures, and other physical facilities of the bottling plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. 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 uses. Only such toxic materials as are

required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the bottling plant. These materials shall be identified, used only in such manner and under conditions as will be safe for their intended uses, and stored in an approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.

2. ANIMAL AND VERMIN CONTROL

No animals or birds shall be allowed in any area of the bottling plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues. Insecticides and rodenticides shall be properly labeled and stored in a approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.

SECTION VI. EQUIPMENT AND UTENSILS

A. All bottling plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained and kept clean and in good repair. The design, construction and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal and glass fragments, contaminated water, or any other contaminants.

B. All equipment shall be so installed and maintained to facilitate the cleaning of the equipment and all adjacent spaces.

C. All food-contact surfaces shall be corrosion-resistant when in contact with food and shall be made of nontoxic materials and designed to withstand the environment of their intended use and any corrosive action by the food, cleaning compounds and sanitizing agents. Seams on food-contact surfaces shall be smoothly bonded.

D. All equipment shall be designed to prevent food-contact surfaces from being contaminated by clothing or personal contact.

E. Mixing and storage tanks shall be provided with approved tight-fitting covers which shall be kept closed when in use, except when blending is being conducted.

F. All equipment shall be constructed so that drip or condensation from fixtures, ducts, pipes, etc., does not contaminate food, food-contact surfaces or food-packaging materials.

G. All equipment that is in the manufacturing or food-handling areas and that does not come in contact with food shall be so constructed that it can be kept in a clean condition.

H. Approved washable covers shall be provided over exposed containers prior to filling and between filling and sealing in all areas where contamination is reasonable possible.

SECTION VII. PRODUCTION AND PROCESS CONTROLS

A. PROCESS CONTROLS.

1. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging and storing of food shall be conducted in accordance with adequate sanitation principles. During delivery of bulk ingredients in tanks, to prevent collapse of the tank, the manhole may be opened, but shall be provided with an air filter to prevent contamination.

2. Appropriate quality control operators should be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the bottling plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source.

3. Chemical, microbiological, or extraneous material testing procedures shall be used, where necessary, to identify sanitation failures or possible food contamination. All food that has become adulterated shall be rejected, or if permissible, treated or processed to eliminate the contamination.

4. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into soft drinks and bottled waters and shall be stored under conditions that will protect against contamination and minimize deterioration.

5. Raw materials and other ingredients shall be properly labeled and stored in containers designed and constructed so as to protect against contamination.

6. Raw materials and ingredients shall be kept at such temperature and relative humidity to prevent the food from becoming adulterated.

7. The bottler shall maintain in the plant a current certification or notification of approval from the Department which shall constitute approval of the water source and which shall be available for inspection, and a copy of which shall be made available to consumers upon request.

8. Soft drink and bottled water products shall not be stored, transported, processed or bottled through equipment or lines used for any non-food product.

9. Soft drink and bottled water production, including transporting, processing, packaging, and storage shall be conducted under such conditions and controls as are necessary to minimize the potential for microbiological contamination of the finished product.

10. Bottled water shall be subject to effective germicidal treatment by ozonation or carbonation at a minimum of three volumes of carbon dioxide or other equivalent disinfection approved by the Department.

11. Weekly in-house total coliform monitoring on finished product of each bottled water product type and quarterly rinse/swab tests on bottled water containers (incoming as well as those immediately from the washer) and closures shall be performed in-house or by an approved laboratory as stipulated in 21 CFR Section 129.80. For microbiological contaminants (total coliform), analyze a representative sample from a batch or segment of a continuous production run for each bottled water product type produced by the plant.

12. Samples of source water shall be taken and analyzed by the bottled water plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every four

years for radiological contaminants. Firms that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants.

13. For chemical, physical, and radiological contaminants, a representative sample from a batch or segment of continuous production run for each type of finished bottled water product produced by the plant shall be analyzed annually to assure that the product(s) complies with current FDA standards.

14. Bottled water may be used as an ingredient in beverages (e.g. diluted juices, flavored bottled waters).

15. Spring water shall be collected only at the spring or through a borehole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified and such identification shall be maintained in the company's records. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request to the Department, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the borehole.

16. Fluoride may be optionally added to bottled water within the limitations established in 21 CFR Section 165.110. Firms may manufacture nonstandardized bottled water products with ingredients such as minerals for flavor. The common usual name of the resultant product must reflect these additions.

B. CLEANING AND SANITIZING OF EQUIPMENT AND UTENSILS

All utensils and food-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Non food-contact surfaces of equipment used in the operation of bottling plants shall be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles and other debris. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and food-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruptions during which such utensils and food-contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the food-contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. All cleaning and sanitizing agents shall be free of undesirable microorganisms, shall be safe and adequate under the conditions of use, shall have labels which properly identify the contents, and shall be properly stored. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment. All cleaned and sanitized equipment and utensils shall be transported and stored to assure complete drainage and stored in a manner that protects the food-contact surfaces from contamination.

C. APPROVED METHODS OF SANITIZATION.

1. Hot water may be used if the cleaned surfaces to be sanitized are in contact with water at a temperature not less than 170°F. for a period of not less than two minutes. In treating pipelines and fillers, the water issuing from the outlet must be a minimum of 170°F. for a least two minutes.

2. Chlorine may be used if the cleaned surfaces to be sanitized are in contact with a solution containing not less than fifty parts per million of available chlorine as a hypochlorite and at a temperature of at least 75°F. for not less than one minute or to an equivalent chlorine concentration/time period process approved by the Department.

3. Other methods of sanitization may be used if approved by the Department.

D. RETURNABLE CONTAINER CLEANING.

1. All returnable containers shall be adequately, mechanically washed and sanitized prior to filling. Unless the containers are sealed after washing, they shall be washed immediately prior to filling. Hand cleaning of containers is prohibited except as a preliminary to subsequent mechanical washing.

2. METAL AND GLASS CONTAINERS

(a) All metal and glass containers shall be exposed to a minimum 3% alkali solution of which not less than 60% is caustic soda (sodium hydroxide) by an approved automatic mechanical method for a period of not less than five minutes at a temperature of not less than 130°F., or to an equivalent cleaning and sanitizing process approved by the Department.

(b) Containers shall be rinsed of all caustic soda with potable water.

3. POLYCARBONATE CONTAINERS

(a) Polycarbonate containers shall be cleaned with approved non-caustic detergents at their required concentrations by an approved mechanical method.

(b) An approved sanitizing rinse consisting of chlorine, bromine, iodine, quaternary ammonia or ozonated water at the proper approved temperature/time/concentration must follow the cleaning cycle.

4. A permanent record of key operating parameters of the container washer should be maintained. These records or logs should include, but not limited to wash temperatures, concentrations of cleaners, concentrations of sanitizers, lack of carryover of cleaners or caustic in bottles, and maintenance on the washer. Tests on cleaner/sanitizer concentrations and carryover should be carried out at start-up and regularly thereafter throughout the shift. All maintenance on washer should be recorded, such as cleaning or aligning spray jets. All records shall be kept on file at least two years for regulatory inspection. Each washer shall be equipped with an indicating thermometer.

E. SINGLE-SERVICE CONTAINERS.

1. Single-service containers shall be manufactured from food-grade materials that do not impart odors or tastes to the product nor contaminate the product with microorganisms, toxic or injurious substances.

2. Single-service containers shall be packaged and stored in a manner approved by the Department prior to filling.

3. Unless otherwise approved by the Department, all single-service containers shall be inverted and rinsed with potable water, treated by filtered compressed air or vacuumed to remove dust prior to filling.

F. INSPECTION OF RETURNABLE CONTAINERS.

1. BOTTLES

(a) All empty bottles shall be visually inspected immediately after the final rinse of the washing operation for defects, chips, foreign objects, and unclean product contact surfaces as the bottles pass on a conveyor before a well-illuminated background at a speed slow enough for the inspector to achieve high efficiency. Bottles used exclusively for bottled water coolers do not have to pass before a well-illuminated background, but should be visually inspected prior to reuse.

(b) Dirty bottles shall be removed from the production line and either destroyed or rewashed. Defective bottles shall be removed from the production line and destroyed. When inspectors break bottles for cullet, adequate protection shall be provided for exposed bottles in the immediate area to prevent glass fragments from entering them.

(c) Electronic inspection devices can be used in addition to visual inspection; however, electronic inspection devices shall not be substituted for visual inspection of returnable bottles without the approval of the Department. Inspectors shall have good eyesight, with or without corrective lenses, and shall be rotated to noninspection work as often as is necessary to maintain high efficiency.

(d) Returnable bottles shall not be used where their condition or design may prevent proper inspection of the contents thereof.

2. METAL CANISTERS

(a) All metal canisters shall be visually inspected immediately after the final rinse of the washing operation for the presence of foreign objects or unclean product contact surfaces.

(b) Unclean canisters shall be either immediately returned to the washer or removed to the storage area for unclean canisters.

G. CONTAINER CLOSURES.

1. Container closures shall be manufactured from food-grade materials which do not impart odors or tastes to the product nor contaminate the product with microorganisms, toxic or injurious substances.

2. Container closures shall be received by the bottling plant in an undamaged package sealed by the manufacturer.

3. All container closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination. Closures which have been touched on the inner side by the operator, as may occur while adjusting equipment, shall be discarded.

4. Container closures not used during the period of processing operations shall be resealed in their original container or stored in an approved tightly covered container.

5. Only new container closures shall be used.

H. FILLING AND SEALING.

1. Containers shall be filled and sealed with approved mechanical equipment. Manual filling and sealing shall be prohibited, except when otherwise approved by the Department for package sizes in which mechanical sealing equipment is not yet readily available.

2. Filling equipment which fills glass containers under pressure should be provided with an adequate shield to protect against broken glass entering unsealed containers. Whenever a glass bottle breaks while being filled or sealed, the machinery involved shall be stopped and all broken glass shall be removed from parts which touch the opening of bottles or which contact the product. This shall be performed in such a manner to protect against transferring broken glass into nearby bottles which have exposed openings.

3. No person or his clothing shall come in contact with any portion of the container or equipment which might result in contamination of the product.

4. The contents of all imperfectly sealed containers shall be discarded.

I. INGREDIENTS AND LABELING.

1. All soft drinks and bottled waters shall be prepared with approved ingredients that meet all applicable ingredient regulations as defined by the United States Food and Drug Administration.

2. All soft drink and bottled water labeling shall conform to applicable federal and state labeling laws.

SECTION VIII. EXAMINATION AND CONDEMNATION OF UNWHOLESOME OR CONTAMINATED RAW MATERIALS OR FINISHED PRODUCT.

A. Samples of ingredients, drinks, and other substances shall be taken and examined by the Department as often as may be necessary for the detection of unwholesomeness or adulteration.

B. The Department may condemn and forbid the sale of, or cause to be removed and destroyed, any ingredients or products which are unwholesome or adulterated.

SECTION IX. ENFORCEMENT PROCEDURES

A. PERMITS

It shall be unlawful for any person to manufacture soft drinks or bottled waters in South Carolina without a valid permit issued by the Department for the specific bottling plant. Permits are not transferable.

B. ISSUANCE OF PERMITS

1. Any person desiring to manufacture soft drinks or bottled waters in South Carolina shall make written application for a permit on the appropriate application form provided by the Department. This form shall include name and address of bottling plant's owner, location and type of facility and products to be manufactured, applicant's signature and such other information deemed necessary by the Department to determine compliance with this regulation.

2. A permit is valid as long as the bottling plant continues in operation under the same ownership or until the permit is revoked or suspended.

3. Any person whose application for a permit is denied under this regulation may request that a hearing be held as required by law.

C. SUSPENSION OF PERMIT

1. Permits may be suspended temporarily by the Department for repeated violation, for total number of violations, or for interference with the Department in the performance of its duty. Prior to permit suspension, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be suspended and that the permit shall be suspended at the end of the 15 days following service of such notice unless a written request for a hearing is filed with the Department by the permit holder within such 15-day period. If no written request is filed within 15 days, the permit is suspended and bottling operations shall immediately cease. If the hearing upholds the finds of the Department, the permit shall be suspended until the reasons for the suspension have been corrected.

2. The Department may without warning, notice, or hearing suspend the permit to operate a bottling plant when it is determined that the operation of the bottling plant constitutes an imminent hazard to public health. Following immediate permit suspension, all bottling operations shall immediately cease. The Department shall promptly notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit was suspended, and that an opportunity for a hearing will be provided if a written request for a hearing is filed with the Department by the permit holder within 15 days. If no written request for a hearing is filed within 15 days, the suspension is sustained. During the hearing process, the permit shall remain suspended unless the imminent health hazard has been corrected.

3. Hearings on suspension of permits as provided for in this regulation shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, Sections 1-23-310 et seq., 1976 Code of Laws of South Carolina as amended, and applicable regulations.

D. REVOCATION OF PERMIT.

1. The permit may be revoked for failure to correct deficiencies within prescribed time limits or for repeated violations of any of the requirements of this regulation, or for the interference with the health authority in the performance of duty.

2. Prior to revocation, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be revoked and that the permit shall be revoked at the end of the 15 days following service of such notice unless a written request is filed with the Department by the permit holder within such 15-day period.

3. Any person whose permit is revoked shall not be eligible to apply for repermitting within one year from the date of revocation. Any person whose permit has previously been revoked and who obtains a subsequent permit and violates the provisions of this regulation, resulting in revocation of the bottling plants permit for the second time, shall not be granted another permit.

4. Hearings on revocation of permits as provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, SC Code Ann. 1-23-310 et seq. (1976, as amended) and applicable regulations.

E. SERVICE OF NOTICES

F. HEARINGS

All hearings provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, SC Code Ann. 1-23-310 et seq. (1976, as amended) and applicable regulations.

G. INSPECTIONS

Inspections of bottling plants shall be performed as frequently as deemed necessary to insure compliance with this regulation.

H. ACCESS

Representatives of the Department, after proper identification, shall be permitted to enter any bottling plant at any reasonable time for the purpose of making inspections to determine compliance with this regulation. The representatives shall be permitted to examine the records of the establishment to ascertain information relative to the purchasing, receiving, and use of such food products or other supplies used in the manufacturing of soft drinks and bottled waters. It shall be unlawful for any representatives of the Department who, in an official capacity, obtain any information under the provisions of this regulation which is entitled to protection as a trade secret (including information as to quantity, quality, source or disposition of soft drinks or bottled water products, or results of inspections or tests thereof) to use such information to their own advantage or to reveal it to any unauthorized person.

I. REPORT OF INSPECTIONS

When an inspection of a bottling plant is conducted, a copy of the completed inspection report form shall be furnished to the permit holder, manager or other duly authorized representative.

J. SUBMISSION OF PLANS

When a bottling plant is constructed or extensively remodeled and when an existing structure is converted for use as a bottling plant, properly prepared plans and specifications for such construction, remodeling, or conversion should be submitted to the Department for review and approval before construction, remodeling, or conversion. The plans and specifications should indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the make and model number of proposed fixed equipment and facilities. The Department shall approve the plans and specifications if they meet the requirements of this regulation. In the absence of plan approval, issuance of the bottling plant permit shall be determined by compliance with all applicable requirements of this regulation.

K. RECIPROCITY

Upon receiving from any person, entity, or any regulatory agency outside this state, a report of a possible violation of this regulation by a permit holder, the Department may conduct such inspection or investigation as it deems appropriate. Upon receiving information that soft drinks or bottled waters manufactured or bottled outside this state and introduced into this state may have been manufactured in violation of applicable state or federal law or not in conformance with prevailing and applicable standards and good public health practices, the Department may notify appropriate regulatory authorities located outside this state and request that such authorities take appropriate action.

L. OUT-OF-STATE IMPORTS

Due to additional FDA laboratory testing requirements for bottled water products, out-of-state water bottlers should submit the following to the Department: (a) a certification signed by the applicable regulatory agency with jurisdiction over the bottling in the state of origin stating that the plant(s) is permitted or licensed as required, the source water supply meets all EPA public drinking water requirements, and is operated and maintained in a sanitary manner based on previous plant inspection(s); (b) the name, address, and phone number(s) of all plant(s) manufacturing bottled products for sale in South Carolina; (c) a copy of the latest finished bottled water product water analyses (total coliform, inorganic, organic, radiological); and (d) the location(s) where the product(s) may be sampled in South Carolina.

M. OUT-OF-COUNTRY IMPORTS

For bottled water products imported from outside the United States, permission should be obtained from the Department prior to initiating the importation of bottled water products into South Carolina. This should include a certification signed by the applicable regulatory agency in the country of origin with jurisdiction over the bottling that (a) describes the requirements of said country for the source, bottling facility, treatment, bottling practices, and finished products; (b) states the date of the last officially authorized inspection by the applicable regulatory agency or acceptable third-party inspection organization and review of said source, facility, treatment, bottling practices, and final products; (c) certifies that said source, facility, treatment, bottling practices, and finished products meet the standards of the country of origin except those that are in conflict with U.S. State and Federal laws and regulations; and (d) where the product(s) may be sampled in South Carolina.

N. RECALL

Each bottling plant operator shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the operator or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the bottling supplier, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the bottling supplier to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The bottling supplier shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

O. ENFORCEMENT PROVISIONS

This regulation is issued under the authority of South Carolina Code Ann. Section 44-1-140 (1976, as amended) and shall be enforced by the Department.

P. PENALTIES

Violation of this regulation shall be punishable in accordance with South Carolina Code Ann. Section 44-1-150 (1976, as amended).