

Illinois General Assembly - Full Text of Public Act 093-0866
Public Act 093-0866

AN ACT in relation to public health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title

This Act may be cited as the Safe Bottled Water Act.

Section 5. Definitions

In this Act:

"Bottled water" means any water that is placed in a sealed container at a water-bottling plant to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. "Bottled water" does not include water packaged with the approval of the Department for use in a public emergency.

"Department" means the Department of Public Health.

"Private water source" means a privately owned source of water in Illinois, other than a public water system or private water system as defined in the Illinois Groundwater Protection Act, that is used for bottled or vended water and meets the requirements of an approved source for bottled water as defined in Section 129.3 of Title 21 of the Code of Federal Regulations.

"Retail water facility" means any commercial establishment where vended water is sold, and placed in customers' containers, or placed in containers sold or given to customers who come to the establishment to obtain water.

"Vended water" means any water that is dispensed by a water-vending machine or retail water facility, or water from a private water source, and that is dispensed by a water-vending machine, retail water facility, water hauler, or any other person or facility for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. "Vended water" does not include

water from a public water system that has not undergone additional treatment. Water sold without further treatment is not "vended water".

"Water-bottling plant" means any facility in which bottled water is produced.

"Water-vending machine" means any self-service device that, upon insertion of a coin, coins, or token, or upon receipt of payment by any other means, dispenses a unit volume of water to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

Section 10. Licenses required

- (a) No person may operate a water-bottling plant or a private water source in this State, except pursuant to a license issued by the Department. Bottled water must be processed in conformance with 21 CFR Part 129 and must conform to 21 CFR Part 165. If a person has a valid water-bottling plant license issued by the Department, additional license fees for a private water source operator based and operating at the same address shall not be required.
- (b) Any bottled water produced by a private water source or water-bottling plant that is not licensed in compliance with this Act is misbranded and may be embargoed.
- (c) It is unlawful for a water bottler, water distributor, water-vending machine owner, retail water facility, or private water source operator to sell or otherwise distribute water that is unsafe for use or that is adulterated or misbranded as provided in the Illinois Food, Drug and Cosmetic Act.
- (d) The licensing of activities relating to bottled water as provided in this Section is an exclusive power and function of the State. A home rule unit may not license any activities relating to bottled water that are licensed under this Section. This subsection is a denial and limitation of home rule powers and functions under subsection (h) of Section 6 of Article VII of the Illinois Constitution.

Section 15. Inspections and related activities.

- (a) In order to carry out the purposes of this Act, any duly authorized representative of the Department may, at any reasonable hour of the day, do any of the following:
 - (1) Enter and inspect a licensed facility or any place where bottled water or vended water records are stored, kept, or maintained.
 - (2) Inspect and copy any records, reports, test results, or other information required to implement this Act.
 - (3) Obtain samples of the water supply and finished product.
- (b) The Department shall inspect every water-bottling plant and private water source at least once each year. The Department shall provide an opportunity for a representative of the water-bottling plant or private water source operator to accompany the Department's representative during the inspection.
- (c) Any person who prevents, interferes with, or attempts to impede in any way any duly authorized representative of the Department from undertaking any activity authorized by this Section is guilty of a Class A misdemeanor.

Section 20. Water intended for bottling; storage, transportation, and processing.

- (a) Water intended for bottling shall not be stored, transported, processed, or bottled through equipment or lines used for any non-food product.
- (b) Water intended for bottling shall not be stored, transported, processed, or bottled through equipment or lines used for any non-beverage food, except that filling equipment may be used for non-beverage foods in accordance with the following requirements:
 - (1) When filling equipment designed for cleaning in place is utilized for non-beverage foods, that equipment must be thoroughly cleaned and sanitized in place in accordance with procedures specified by the

manufacturer and in 21 CFR Part 129 prior to being used for bottled water.

- (2) Fillers not designed for cleaning in place must be completely disassembled for cleaning and sanitizing prior to being used for bottled water.

Section 25. License fee

The fee for any license issued under this Act is \$150. The fee must be paid to the Department before a license may be issued. Licenses issued under this Act shall be issued annually. Licenses must be renewed annually on or before January 1 of the year for which they are issued. The Department may impose an additional fee of \$50 on a person who submits an application for a license after the deadline. The Department shall use all fees received under this Act for the purpose of recouping the costs of providing the services required to be provided by the Department under this Act.

Section 30. Water-bottling plants located outside Illinois.

Every water-bottling plant located outside Illinois that sells or distributes bottled water in Illinois must annually register with the Department. The fee for registration under this Act is \$150. The Department may impose an additional fee of \$50 on an out-of-state water-bottling plant that registers after the deadline set by the Department.

Section 35. Safe Bottled Water Fund

The Safe Bottled Water Fund is established as a special fund in the State treasury. All moneys received by the Department under this Act shall be deposited into the fund. Moneys in the fund shall be used by the Department, upon appropriation, for the purpose of administering this Act.

Section 40. Denial, revocation, or suspension of license

- (a) The Department may deny any license application or revoke or suspend any license issued under this Act for cause. The Department shall inform the applicant or license holder of the denial, revocation, or suspension in writing, stating with particularity the reasons for the denial,

revocation, or suspension. The Department shall afford the applicant or license holder an opportunity for a hearing in accordance with the Illinois Administrative Procedure Act.

- (b) For purposes of this Section, "cause" means a violation of any provision of this Act or any regulation adopted pursuant to this Act.

Section 45. Potential contamination

- (a) Upon a determination by the Department that a particular water source is subject to potential contamination, the Department shall notify the appropriate bottler, distributor, or vendor of bottled water, owner or operator of a water-vending machine, water hauler, retail water facility operator, or private water source operator of the specific contaminants or class of contaminants that pose a potential health risk.
- (b) Within 7 days after notification by the Department, the bottler, distributor, or vendor of bottled water, owner or operator of a water-vending machine, water hauler, retail water facility operator, or private water source operator must conduct an analysis of the water source and submit the results of the analysis to the Department.
- (c) If evidence of contamination is found, the Department may, by order, require the bottler of bottled water, owner or operator of a water-vending machine, or private water source operator to conduct an analysis of the finished water product for the contaminants of concern in accordance with conditions specified by the Department. The water analysis must be conducted and reported on an annual basis, unless the Department finds that reasonable action requires either more frequent or less frequent analysis.

Section 50. Testing laboratories

All testing of bottled water, bottled water sources, water distributed by water haulers, water from retail water facilities, and water from vending machines must be done by competent laboratories approved by the Department or another state's regulatory agency.

Section 55. Water packaged for use in public emergencies

- (a) The Department, by its written permission, may allow a person to package water for use in public emergencies without obtaining a water bottling license if the emergency has resulted in the interruption of, or has compromised the quality of, the public drinking water supply. The Department's permission may authorize the suspension of any provision of this Act and related regulations.
- (b) The Department may at any time change or impose on the permittee any requirements, such as requirements concerning testing, equipment, and documentation, that the Department deems necessary to protect public health, but in doing so, the Department must consider the effect of those requirements in light of the urgency of the situation. The Department may grant or withdraw this permission at any time.
- (c) Packing, distribution, and use of water under a permit shall be allowed only during the emergency period and shall end upon the restoration of adequate public drinking supplies as determined by the Department. Distribution of the packaged water shall be limited to the area affected. Water so packaged shall be prominently labeled "drinking water", "for emergency use only", and "not for sale", or similar wording approved by the Department.
- (d) This Section shall not be construed to restrict licensed water-bottling plants from providing water processed in accordance with this Act in emergency situations.

Section 60. Violation; penalty

A person who commits a violation of this Act other than a violation of subsection (c) of Section 15 is guilty of a petty offense and subject to a fine of not more than \$1,000.

Section 90. The State Finance Act is amended by adding

Section 5.625 as follows:

(30 ILCS 105/5.625 new)

Section 5.625. The Safe Bottled Water Fund.

Section 99. Effective date

This Act takes effect January 1, 2005.

TITLE 21--FOOD AND DRUGS
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION

**PART 110 CURRENT GOOD MANUFACTURING PRACTICE IN
MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD**

Subpart A -- General Provisions

- §110.3 Definitions.
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- §110.20 Plant and grounds.
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- §110.37 Sanitary facilities and controls.

Subpart C -- Equipment

- §110.40 Equipment and utensils.

Subpart D [Reserved]

Subpart E -- Production and Process Controls

- §110.80 Processes and controls.
- §110.93 Warehousing and distribution.

Subpart F [Reserved]

Subpart G -- Defect Action Levels

- §110.110 Natural or unavoidable defects in food for human use that present no health hazard.

Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

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PART 110 CURRENT GOOD MANUFACTURING PRACTICE IN
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Subpart A -- General Provisions

Section 110.3 Definitions

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.
- (b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) *Blanching*, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) *Critical control point* means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) *Food* means food as defined in section 201(f) of the act and includes raw materials and ingredients.

- (g) *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.
- (h) *Lot* means the food produced during a period of time indicated by a specific code.
- (i) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective “microbial” instead of using an adjectival phrase containing the word microorganism.
- (j) *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- (k) *Plant* means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- (l) *Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- (m) *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

- (n) *Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.
- (o) *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- (p) *Shall* is used to state mandatory requirements.
- (q) *Should* is used to state recommended or advisory procedures or identify recommended equipment.
- (r) *Water activity (aw)* is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Section 110.5 Current good manufacturing practice

- (a) The criteria and definitions in this part shall apply in determining whether a food is adulterated
 - (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or
 - (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

- (b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

Section 110.10 Personnel

The plant management shall take all reasonable measures and precautions to ensure the following:

- (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 there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. 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. The methods for maintaining cleanliness include, but are not limited to:
 - (1) Wearing outer garments suitable to 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.

- (4) Removing all unsecured jewelry and other objects that 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 may be covered by material which 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, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
 - (6) Wearing, where appropriate, in an effective manner, hair nets, 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 of 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 insanitary practices.

- (d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Section 110.19 Exclusions

- (a) The following operations are not subject to this part:
Establishments engaged solely in the harvesting, storage, or distribution of one or more “raw agricultural commodities,” as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.
- (b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B -- Buildings and Facilities

Section 110.20 Plant and grounds

- (a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. 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 within the immediate vicinity of the 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 contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
 - (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

- (b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:
- (1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

- (2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.
- (3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:
 - (i) Using protective coverings.
 - (ii) Controlling areas over and around the vessels to eliminate harborages for pests.
 - (iii) Checking on a regular basis for pests and pest infestation.
 - (iv) Skimming the fermentation vessels, as necessary.
- (4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

- (5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
- (6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
- (7) Provide, where necessary, adequate screening or other protection against pests.

Section 110.35 Sanitary operations

- (a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- (b) *Substances used in cleaning and sanitizing; storage of toxic materials.*
 - (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- (i) Those required to maintain clean and sanitary conditions;
 - (ii) Those necessary for use in laboratory testing procedures;
 - (iii) Those necessary for plant and equipment maintenance and operation; and
 - (iv) Those necessary for use in the plant's operations.
- (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.
- (c) *Pest control.* No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.
- (d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.
- (1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

- (2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
 - (3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.
 - (4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food contact surfaces.
 - (5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.
- (e) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Section 110.37 Sanitary facilities and controls

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

- (a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.
- (b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:
 - (1) Carry sufficient quantities of water to required locations throughout the plant.
 - (2) Properly convey sewage and liquid disposable waste from the plant.
 - (3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating 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) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.
- (c) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.
- (d) *Toilet facilities.* Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

- (1) Maintaining the facilities in a sanitary condition.
 - (2) Keeping the facilities in good repair at all times.
 - (3) Providing self-closing doors.
 - (4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).
- (e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
- (1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
 - (2) Effective hand-cleaning and sanitizing preparations.
 - (3) Sanitary towel service or suitable drying devices.
 - (4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
 - (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
 - (6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

- (f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C -- Equipment

Section 110.40 Equipment and utensils

- (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
- (b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
- (c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.
- (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
- (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

- (f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.
- (g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D [Reserved]

Subpart E -- Production and Process Controls

Section 110.80 Processes and controls

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles.

Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the 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. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

- (a) *Raw materials and other ingredients.*
 - (1) 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 food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

- (2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
- (3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.
- (4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.
- (5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

- (6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.
 - (7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.
- (b) *Manufacturing operations.*
- (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
 - (2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.
 - (3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:
 - (i) Maintaining refrigerated foods at 45 °F (7.2 °C) or below as appropriate for the particular food involved.

- (ii) Maintaining frozen foods in a frozen state.
 - (iii) Maintaining hot foods at 140 °F (60 °C) or above.
 - (iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.
- (4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.
- (5) Work-in-process shall be handled in a manner that protects against contamination.
- (6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.
- (7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.
- (8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

- (9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.
- (10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.
- (11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.
- (12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:
 - (i) Using ingredients free of contamination.

- (ii) Employing adequate heat processes where applicable.
 - (iii) Using adequate time and temperature controls.
 - (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
 - (v) Cooling to an adequate temperature during manufacturing.
 - (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.
- (13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:
- (i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
 - (ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
 - (iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter.
 - (iv) Providing physical protection from contamination, particularly airborne contamination.
 - (v) Using sanitary handling procedures.
- (14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- (i) Monitoring the aw of food.
 - (ii) Controlling the soluble solids-water ratio in finished food.
 - (iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the aw of the food does not increase to an unsafe level.
- (15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
- (i) Monitoring the pH of raw materials, food in process, and finished food.
 - (ii) Controlling the amount of acid or acidified food added to low-acid food.
- (16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
- (17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

Section 110.93 Warehousing and distribution

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G -- Defect Action Levels

Section 110.110 Natural or unavoidable defects in food for human use that present no health hazard

- (a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
- (b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
- (c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- (d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

- (e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

TITLE 21--FOOD AND DRUGS
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION

PART 129 PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

Subpart A -- General Provisions

§129.1 - Current good manufacturing practice.

§129.3 - Definitions.

Subpart B -- Buildings and Facilities

§129.20 - Plant construction and design.

§129.35 - Sanitary facilities.

§129.37 - Sanitary operations.

Subpart C -- Equipment

§129.40 - Equipment and procedures.

Subpart D [Reserved]

Subpart E -- Production and Process Controls

§129.80 - Processes and controls.

Authority: 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

Source: 42 FR 14355, Mar. 15, 1977, unless otherwise noted.

TITLE 21--FOOD AND DRUGS
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION

PART 129 PROCESSING AND BOTTLING OF BOTTLED DRINKING
WATER

Subpart A -- General Provisions

Section 129.1 Current good manufacturing practice

The applicable criteria in part 110 of this chapter, as well as the criteria in §§129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

Section 129.3 Definitions

For the purposes of this part, the following definitions apply:

- (a) Approved source when used in reference to a plant's product water or operations water means a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, 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 applicable laws and regulations of State and local government agencies having jurisdiction. The presence in the plant of current certificates or notifications of approval from the government agency or agencies having jurisdiction constitutes approval of the source and the water supply.
- (b) Bottled drinking water means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.
- (c) 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.
- (d) Multiservice containers means containers intended for use

more than one time.

- (e) Nontoxic materials means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.
- (f) 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.
- (g) Primary container means the immediate container in which the product water is packaged.
- (h) Product water means processed water used by a plant for bottled drinking water.
- (i) Shall and should. "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.
- (j) Shipping case means a container in which one or more primary containers of the product are held.
- (k) Single-service container means a container intended for one time usage only.
- (l) Unit package means a standard commercial package of bottled drinking water, which may consist of one or more containers.

[42 FR 14355, Mar. 6, 1977, as amended at 44 FR 12175, Mar. 6, 1979]

Subpart B -- Buildings and Facilities

Section 129.20 Plant construction and design

- (a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.
- (b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.
- (c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.
- (d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.
- (e) Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

Section 129.35 Sanitary facilities

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

- (a) Product water and operations water

- (1) Product water. The product water supply for each plant shall be 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 of the government agency or agencies having jurisdiction.
- (2) Operations water. If different from the product water supply, the operations 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 of the government agency or agencies having jurisdiction.
- (3) Product water and operations water from approved sources.
 - (i) Samples of source water are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for microbiological contaminants at least once each week. This sampling is in addition to any performed by government agencies having jurisdiction. Records of approval of the source water by government agencies having jurisdiction and of sampling and analyses for which the plant is responsible are to be maintained on file at the plant.
 - (ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in § 165.110(b) of this chapter.

- (iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories).
- (4) Source water testing exemptions.
- (i) 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 (40 CFR parts 141 and 143), for the testing requirements of § 129.35(a)(3).
 - (ii) Firms that do not use a public water system as the source of their water may reduce the frequency of their testing of that source, as well as the number of chemical contaminants for which they test the source water, if they can document that such reduction is consistent with a State-issued waiver under EPA regulations (40 CFR parts 141 and 143).
 - (iii) Firms that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone do not have to test their source water for the residual disinfectants and DBP's listed in § 165.110(b)(4)(iii)(H) of this chapter. Firms that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants and the DBP's listed in § 165.110(b)(4)(iii)(H) that are likely to result from such treatment.
 - (iv) The finished bottled water must comply with bottled water quality standards (21 CFR 165.110(b)) and section 402(a)(1) of the act dealing with adulterated foods.

- (b) Air under pressure. Whenever air under pressure is directed at product water or a product water-contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and should not adversely affect the flavor, color, or odor of the water.
- (c) Locker and lunchrooms. 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.

[42 FR 14355, Mar. 15, 1977, as amended at 44 FR 12175, Mar. 6, 1979; 60 FR 57123, Nov. 13, 1995; 66 FR 16865, Mar. 28, 2001]

Section 129.37 Sanitary operations

- (a) The product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.
- (b) After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.
- (c) Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

- (d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

Subpart C -- Equipment

Section 129.40 Equipment and procedures

- (a) Suitability.
 - (1) All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.
 - (2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbent material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.
- (b) Design. Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

Subpart D [Reserved]

Subpart E -- Production and Process Controls

Section 129.80 Processes and controls

- (a) Treatment of product water. All treatment of product water by distillation, ion-exchanging, filtration, 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. 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. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

- (b) Containers.
 - (1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

 - (2) 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.

- (c) Cleaning and sanitizing solutions. Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant.

- (d) Sanitizing operations. 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:
 - (1) Steam in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.
 - (2) Hot water in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.
 - (3) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 parts per million of available chlorine at 57 °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 57 °F or its equivalent in bactericidal action.
 - (4) 0.1 part per million ozone water solution in an enclosed system for at least 5 minutes.
 - (5) When containers are sanitized using a substance other than one provided for in § 178.1010 of this chapter, 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 paragraph (d)(3) of this section.

- (e) Unit package 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.

- (f) Filling, capping, or sealing. 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 or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 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 conformance with those recognized by the government agency or agencies having jurisdiction. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

- (g) Compliance procedures. A quality standard for bottled drinking water is established in § 165.110(b) of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

- (1) For bacteriological purposes, take and analyze at least once a week a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product.
 - (2) For chemical, physical, and radiological purposes, take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample(s) consists of primary containers of product of unit packages of product.
 - (3) Analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.
- (h) Record retention. All records required by §§ 129.1, 129.20, 129.35, 129.37, 129.40, and 129.80 shall be maintained at the plant for not less than 2 years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.

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TITLE 21--FOOD AND DRUGS

SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION

PART 165 BEVERAGES

Subpart A -- General Provisions

§165.3 - Definitions.

Subpart B -- Requirements for Specific Standardized Beverages

§165.110 - Bottled water.

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TITLE 21--FOOD AND DRUGS
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION

PART 165 **BEVERAGES**

Subpart A -- General Provisions

Section 165.3 Definitions

- (a) A *lot* is:
 - (1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.
 - (2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.
- (b) A *sample* consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.
- (c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

Subpart B -- Requirements for Specific Standardized Beverages

Section 165.110 Bottled water

(a) *Identity*—

- (1) *Description.* Bottled water is 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. Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). 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.” The processing and bottling of bottled water shall comply with applicable regulations in part 129 of this chapter.
- (2) *Nomenclature.* The name of the food is “bottled water,” “drinking water,” or alternatively one or more of the following terms as appropriate:
 - (i) The name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer is “artesian water” or “artesian well water.” Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.
 - (ii) The name of water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure is “ground water.” Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.

- (iii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be “mineral water.” 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.
- (iv) The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of “purified water” in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. (Copies may be obtained from the United States Pharmacopial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), may be “purified water” or “demineralized water.” Alternatively, the water may be called “deionized water” if the water has been processed by deionization, “distilled water” if it is produced by distillation, “reverse osmosis water” if the water has been processed by reverse osmosis, and “___ drinking water” with the blank being filled in with one of the defined terms describing the water in this paragraph (e.g., “purified drinking water” or “deionized drinking water”).

- (v) The name of water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide from the source that it had at emergence from the source may be “sparkling bottled water.”

- (vi) The name of water derived from an underground formation from which water flows naturally to the surface of the earth may be “spring water.” Spring water shall be collected only at the spring or through a bore hole 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. 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 appropriate regulatory officials, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

- (vii) The name of water that meets the requirements under “Sterility Tests” <71> in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51. (Copies may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:
http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), may be “sterile water.” Alternatively, the water may be called “sterilized water.”
 - (viii) The name of water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer may be “well water.”
- (3) *Other label statements.*
- (i) If the TDS content of mineral water is below 500 ppm, or if it is greater than 1,500 ppm, the statement “low mineral content” or the statement “high mineral content”, respectively, shall appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch. If the TDS of mineral water is between 500 and 1,500 ppm, no additional statement need appear.

- (ii) When bottled water comes from a community water system, as defined in 40 CFR 141.2, except when it has been treated to meet the definitions in paragraphs (a)(2)(iv) and (a)(2)(vii) of this section and is labeled as such, the label shall state “from a community water system” or, alternatively, “from a municipal source” as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by paragraph (c) of this section, in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.
- (iii) When the label or labeling of a bottled water product states or implies (e.g., through label statements or vignettes with references to infants) that the bottled water is for use in feeding infants, and the product is not commercially sterile under § 113.3(e)(3)(i) of this chapter, the product’s label shall bear conspicuously and on the principal display panel the statement “Not sterile. Use as directed by physician or by labeling directions for use of infant formula.”
- (4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.
- (b) *Quality.* The standard of quality for bottled water, including water for use as an ingredient in beverages (except those described in the labeling as “water,” “carbonated water,” “disinfected water,” “filtered water,” “seltzer water,” “soda water,” “sparkling water,” and “tonic water”), is as follows:

(1) *Definitions.*

- (i) *Trihalomethane* (THM) means one of the 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.
- (ii) *Total trihalomethanes (TTHM)* means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane, and tribromomethane), rounded to two significant figures.
- (iii) *Haloacetic acids* (five) (HAA5) means the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after addition.

- (2) *Microbiological quality.* Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 800 I St. NW., Washington, DC 20001, or a copy may be examined at the National Archives and Records Administration (NARA), or at the Center for Food Safety and Applied Nutrition's Library, 200 C St., SW., Washington, DC, for information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html), meet the following standards of microbiological quality:

- (i) *Multiple-tube fermentation method.* Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or
 - (ii) *Membrane filter method.* Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.
- (3) *Physical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (b)(2) of this section), meet the following standards of physical quality:
- (i) The turbidity shall not exceed 5 units.
 - (ii) The color shall not exceed 15 units. 1
1 Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.
 - (iii) The odor shall not exceed threshold odor No. 3.1
- (4) *Chemical quality.*
- (i) (A) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(4)(i)(B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

SUBSTANCE	CONCENTRATION IN MILLIGRAMS PER LITER
Arsenic	0.05
Chloride \1\	250.0
Iron \1\	0.3
Manganese \1\	0.05
Phenols	0.001
Total dissolved solids \1\	500.0
Zinc \1\	5.0

\1\ Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(B) Analyses conducted to determine compliance with paragraph (b)(4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of “Standard Methods for the Examination of Water and Wastewater,” 15th Ed. (1980), or “Methods for Chemical Analysis of Water and Wastes,” Environmental Monitoring and Support Laboratory (EMSL), EPA-600/4-79-020, March 1983, U.S. Environmental Protection Agency (EPA), both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(C) Analyses for organic substances shall be determined by the appropriate methods set forth below. The methods in paragraphs (b)(4)(i) (C)(1) and (C)(2) of this section are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and are described in “Standard Methods for Examination of Water and Wastewater,” 15th Ed. (1980). Copies may be obtained from the American Public Health Association, 800 I St. NW., Washington DC 20001, and examined at the National Archives and Records Administration (NARA) , or the Center for Food Safety and Applied Nutrition’s Library, 200 C St. NW., Washington DC. For information on the availability of this material at NARA, call 202-741-6030, or go to:
http://www.archives.gov/federal_register/code_

of_federal_regulations/ibr_locations.html. The methods in paragraphs (b)(4)(i)(C)(3) and (C)(4) are cross-referenced in 40 CFR part 141, subpart C, appendix C.

- (1) “Methods for Organochlorine Pesticides in Industrial Effluents;”
- (2) “Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents,” November 28, 1973;
- (3) “Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method;” which is cross-referenced in 40 CFR part 141, subpart C, appendix C;
- (4) “Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction,” which is cross-referenced in 40 CFR part 141, subpart C, appendix C;
 - (ii) (A) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

Table 1

ANNUAL AVERAGE OF MAXIMUM DAILY AIR TEMPERATURES (°F)	FLUORIDE CONCENTRATION IN MILLIGRAMS PER LITER
53.7 and below	2.4
53.8 – 58.3	2.2
58.4 - 63.8	2.0
63.9 – 70.6	1.8
70.7 – 79.2	1.6
79.3 – 90.5	1.4

(B) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(C) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

Table 2

ANNUAL AVERAGE OF MAXIMUM DAILY AIR TEMPERATURES (°F)	FLUORIDE CONCENTRATION IN MILLIGRAMS PER LITER
53.7 and below	1.7
53.8 – 58.3	1.5
58.4 – 63.8	1.3
63.9 – 70.6	1.2
70.7 – 79.2	1.0
79.3 – 90.5	0.8

(D) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

- (iii) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(A) The allowable levels for inorganic substances are as follows:

CONTAMINANT	CONCENTRATION IN MILLIGRAMS PER LITER (OR AS SPECIFIED)
Antimony	.006
Barium	2.
Beryllium	0.004
Cadmium	0.005
Chromium	0.1
Copper	1.0
Cyanide	0.2
Lead	0.005
Mercury	0.002
Nickel	0.1
Nitrate	10 (as nitrogen)
Nitrite	1 (as nitrogen)
Total Nitrate and Nitrite	10 (as nitrogen)
Selenium	0.05
Thallium	0.002

(B) The allowable levels for volatile organic chemicals (VOC`s) are as follows:

CONTAMINANT (CAS REG. NO.)	CONCENTRATION IN MILLIGRAMS PER LITER
Benzene (71-43-2)	0.005
Carbotetrachloride (56-23-5)	0.005
o- Dichlorobenzene (95-50-1)	0.6
p- Dichlorobenzene (106-46-7)	0.075
1,2- Dichloroethane (107-06-2)	0.005
1,1- Dichloroethylene (75-35-4)	0.007
cis- 1,2-Dichloroethylene (156-59-2)	0.07
trans-1,2-Dichloroethylene (156-60-5)	0.1
Dichloromethane (75-09-2)	0.005
1,2-Dichloropropane (78-87-5)	0.005
Ethylbenzene (100-41-4)	0.7
Monochlorobenzene (108-90-7)	0.1
Styrene (100-42-5)	0.1
Tetrachloroethylene (127-18-4)	0.005
Toluene (108-88-3)	1
1,2,4-Trichlorobenzene (120-82-1)	0.07
1,1,1-Trichloroethane (71-55-6)	0.20
1,1,2-Trichloroethane (79-00-5)	0.005
Trichloroethylene (79-01-6)	0.005
Vinyl chloride (75-01-4)	0.002
Xylenes (1330-20-7)	10

(C) The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

CONTAMINANT (CAS REG. NO.)	CONCENTRATION IN MILLIGRAMS PER LITER
Alachlor (15972-60-8)	0.002
Atrazine (1912-24-9)	0.003
Benzo(a)pyrene (50-32-8)	0.0002
Carbofuran (1563-66-2)	0.04
Chlordane (57-74-9)	0.002
Dalapon (75-99-0)	0.2
1,2-Dibromo-3-chloropropane (96-12-8)	0.0002
2,4-D (94-75-7)	0.07
Di(2-ethylhexyl)adipate (103-23-1)	0.4
Dinoseb (88-85-7)	0.007
Diquat (85-00-7)	0.02
Endothall (145-73-3)	0.1
Endrin (72-20-8)	0.002
Ethylene dibromide (106-93-4)	0.00005
Glyphosate (1071-53-6)	0.7
Heptachlor (76-44-8)	0.0004
Heptachlor epoxide (1024-57-3)	0.0002
Hexachlorobenzene (118-74-4)	0.001
Hexachlorocyclopentadiene (77-47-4)	0.05
Lindane (58-89-9)	0.0002
Methoxychlor (72-43-5)	0.04
Oxamyl (23135-22-0)	0.2
Pentachlorophenol (87-86-5)	0.001
PCB's (as decachlorobiphenyl) (1336-36-3)	0.0005
Picloram (1918-02-1)	0.5
Simazine (122-34-9)	0.004
2,3,7,8-TCDD (Dioxin) (1746-01-6)	3x10 ⁻⁸
Toxaphene (8001-35-2)	0.003
2,4,5-TP (Silvex) (93-72-1)	0.05

(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

CONTAMINANT	CONCENTRATION IN MILLIGRAMS PER LITER
Aluminum	0.2
Silver	0.1
Sulfate \1\	250.0

\1\ Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(E) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(A) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(E)(1) through (b)(4)(iii)(E)(13) of this section and described, unless otherwise noted, in "Methods for Chemical Analysis of Water and Wastes," U.S. EPA Environmental Monitoring and Support Laboratory (EMSL), Cincinnati, OH 45258 (EPA-600/4-79-020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

- (1) Antimony shall be measured using the following methods:

- (i) Method 204.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
- (ii) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
- (iii) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

- (iv) Method D-3697-92—“Standard Test Method for Antimony in Water,” contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
- (2) Barium shall be measured using the following methods:
 - (i) Method 208.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (ii) Method 208.1—“Atomic Absorption; direct aspiration,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
 - (iii) Method 200.7—“Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC

20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

- (3) Beryllium shall be measured using the following methods:
- (i) Method 210.2—“Atomic Absorption; Furnace Technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
 - (ii) Method 200.7—“Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
 - (iii) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

- (iv) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
- (4) Cadmium shall be measured using the following methods:
 - (i) Method 213.2—“Atomic Absorption; Furnace Technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
 - (ii) Method 200.7—“Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
- (5) Chromium shall be measured using the following methods:

- (i) Method 218.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
 - (ii) Method 200.7—“Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(I)(ii) of this section.
- (6) Copper shall be measured as total recoverable metal without filtration using the following methods:
 - (i) Method 220.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (ii) Method 220.1—“Atomic Absorption; direct aspiration,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

- (iii) Method 200.7—“Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

- (iv) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

- (v) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

- (7) Cyanide shall be measured using the following methods:
- (i) Method 335.1—“Titrimetric; Spectrophotometric” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (ii) Method 335.2—“Titrimetric; Spectrophotometric” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (iii) Method 335.3—“Colorimetric, Automated UV,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
 - (iv) Method D-2036-91—“Standard Test Methods for Cyanides in Water,” contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
- (8) Lead shall be measured as total recoverable metal without filtration using the following methods:

- (i) Method 239.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
 - (ii) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
 - (iii) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
- (9) Mercury shall be measured using the following methods:
- (i) Method 245.1—“Manual cold vapor technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

- (ii) Method 245.2—“Automated cold vapor technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
- (10) Nickel shall be measured using the following methods:

 - (i) Method 249.1—“Atomic Absorption; direct aspiration,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (ii) Method 249.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
 - (iii) Method 200.7—“Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(i)(ii) of this section.

- (iv) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
 - (v) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
- (11) Nitrate and/or nitrite shall be measured using the following methods:
- (i) Method 300.0—“The Determination of Inorganic Anions in Water by Ion Chromatography—Method 300.0,” EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records

Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

- (ii) Method 353.1—“Colorimetric, automated, hydrazine reduction,” for nitrate only, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (iii) Method 353.2—“Colorimetric, automated, cadmium reduction,” for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (iv) Method 353.3—“Spectrophotometric, cadmium reduction,” for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (12) Selenium shall be measured using the following methods:
- (i) Method 270.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (ii) Method 270.3—“Atomic Absorption; gaseous hydride,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
- (13) Thallium shall be measured using the following methods:

- (i) Method 279.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.
- (ii) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
- (iii) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(1) through (b)(4)(iii)(F)(20) of this section and described, unless otherwise noted, in “Methods for the Determination of Organic Compounds in Drinking Water,” Office of Research and Development, EMSL, EPA/600/4-88/039, December 1988, or in “Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1,” Office of Research and Development, EMSL, EPA/600/4-90/020, July 1990, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these publications are available from NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

- (1) Method 502.1—“Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography,” Rev. 2.0, 1989, (applicable to VOC’s), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (2) Method 502.2—“Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series,” Rev. 2.0, 1989, (applicable to VOC’s), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

- (3) Method 503.1—"Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography," Rev. 2.0, 1989, (applicable to VOC`s), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (4) Method 524.1—"Measurement of Purgeable Organic Compounds in Water by Packed Column Gas Chromatography/Mass Spectrometry," Rev. 3.0, 1989, (applicable to VOC`s), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (5) Method 524.2—"Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 3.0, 1989, (applicable to VOC`s), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (6) Method 504—"1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-Chloropropane (DBCP) in Water by Microextraction and Gas Chromatography," Rev. 2.0, 1989, (applicable to dibromochloropropane (DBCP) and ethylene dibromide (EDB)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (7) Method 505—"Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl (PCB) Products in Water by Microextraction and Gas Chromatography," Rev. 2.0, 1989, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, hexachlorocyclopentadiene, simazine, and as a screen for PCB`s), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

- (8) Method 506—“Determination of Phthalate and Adipate Esters in Drinking Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Gas Chromatography with Photoionization Detection,” applicable to di(2-ethylhexyl) adipate which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (9) Method 507—“Determination of Nitrogen- and Phosphorus-Containing Pesticides in Water by Gas Chromatography with a Nitrogen-Phosphorus Detector,” Rev. 2.0, 1989, (applicable to alachlor, atrazine, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (10) Method 508—“Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector,” Rev. 3.0, 1989, (applicable to chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, and as a screen for PCB`s), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (11) Method 508A—“Screening for Polychlorinated Biphenyls by Perchlorination and Gas Chromatography,” Rev. 1.0, 1989, (used to quantitate PCB`s as decachlorobiphenyl if detected in methods 505 or 508 in paragraph (b)(4)(iii)(F)(7) or (b)(4)(iii)(F)(9) of this section, respectively, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (12) Method 515.1—“Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector,” Rev. 5.0, 1991, (applicable to 2,4-D, 2,4,5-TP (Silvex), pentachlorophenol, dalapon, dinoseb, and picloram), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

- (13) Method 525.1—“Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry,” Rev. 2.2, May 1991, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, pentachlorophenol, benzo(a)pyrene, di(2-ethylhexyl) adipate, endrin, hexachlorobenzene, hexachlorocyclopentadiene, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (14) Method 531.1—“Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization,” Rev. 3.0, 1989, (applicable to carbofuran and oxamyl (vydate)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (15) Method 547—“Determination of Glyphosate in Drinking Water by Direct-Aqueous-Injection HPLC, Post-Column Derivatization, and Fluorescence Detection,” (applicable to glyphosate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (16) Method 548—“Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction, and Gas Chromatography with Electron-Capture Detection,” (applicable to endothall), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (17) Method 549—“Determination of Diquat and Paraquat in Drinking Water by Liquid-Solid Extraction and HPLC with Ultraviolet Detection,” (applicable to diquat), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

- (18) Method 550—“Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Liquid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection,” (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
- (19) Method 550.1—“Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Solid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection,” (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(F) of this section.
- (20) Method 1613—“Tetra- through Octa- Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS,” Rev. A, 1990, EPA, Office of Water Regulations and Standards, Industrial Technology Division, (applicable to 2,3,7,8-TCDD (Dioxin)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from USEPA-OST, Sample Control Center, P.O. Box 1407, Alexandria, VA 22313, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:
http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(G) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(D) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(G)(1) through (b)(4)(iii)(G)(3) of this section and described, unless otherwise noted, in “Methods of Chemical Analysis of Water and Wastes,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

- (1) Aluminum shall be measured using the following methods:
- (i) Method 202.1—“Atomic Absorption; direct aspiration technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (ii) Method 202.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E).
 - (iii) Method 200.7—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
 - (iv) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively

Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(v) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

(2) Silver shall be measured using the following methods:

(i) Method 272.1—“Atomic Absorption; direct aspiration technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(ii) Method 272.2—“Atomic Absorption; furnace technique,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

- (iii) Method 200.7—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,” Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
- (iv) Method 200.8—“Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry,” Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.
- (v) Method 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry,” Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples,” Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E)(1)(ii) of this section.

- (3) Sulfate shall be measured using the following methods:
- (i) Method 300.0—“The Determination of Inorganic Anions in Water by Ion Chromatography—Method 300.0,” EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(11)(i) of this section.
 - (ii) Method 375.1—“Colorimetric, Automated, Chloranilate,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (iii) Method 375.3—“Gravimetric,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or
 - (iv) Method 375.4—“Turbidimetric,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(H) The allowable levels for residual disinfectants and disinfection byproducts are as follows:

SUBSTANCE	CONCENTRATION IN MILLIGRAMS PER LITER
Disinfection byproducts	
Bromate	0.010
Chlorite	1.0
Haloacetic acids (five) (HAA5)	0.060
Total Trihalomethanes (TTHM)	0.080
Residual disinfectants	
Chloramine	4.0 (as C12)
Chlorine	4.0 (as C12)
Chlorine dioxide	0.8 (as C102)

(I) Analysis to determine compliance with the requirements of paragraph (b)(4)(iii)(H) of this section shall be conducted in accordance with an applicable method listed in paragraphs (b)(4)(iii)(I)(1) through (b)(4)(iii)(I)(7) of this section and described in “Method 300.1, Determination of Inorganic Anions in Drinking Water by Ion Chromatography,” Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/118; “Methods for the Determination of Inorganic Substances in Environmental Samples,” U.S. EPA, August 1993, EPA/600/R-93/100; “Methods for the Determination of Organic Compounds in Drinking Water-Supplement II,” U.S. EPA, August 1992, EPA/600/R-92/129; “Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,” U.S. EPA, August 1995, EPA/600/R-95/131; “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., American Public Health Association, 1995; and “Annual Book of ASTM Standards,” vol. 11.01, American Society for Testing and Materials, 1996, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the following publications are available from the National Technical Information Service (NTIS): EPA/600/R-95/131 (NTIS number PB95-261616), EPA/600/R-92/129 (NTIS number PB92-207703), EPA/600/R-93/100 (NTIS number PB94-121811), and EPA/600/R-98/118 (NTIS number PB98-169196). NTIS can be contacted at NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, 1-800-553-6847 or 703-605-6000, www.ntis.gov. Copies of the publication EPA/600/R-98/118 are also available from the Chemical Exposure Research Branch, Microbiological and Chemical Exposure Assessment Research Division, National Exposure Research Laboratory, U.S. EPA, Cincinnati, OH 45268, 513-569-7757, (FAX) 513-569-7757. Copies of “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., are available from the American Public

Health Association, 1015 15th Street, NW., Washington, DC 20005. All of the publications cited in paragraph (b)(4)(iii)(I) of this section may be examined at the National Archives and Records Administration (NARA), or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740. . For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies of "Annual Book of ASTM Standards," 1996, vol. 11.01, are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Office of the Federal Register. Copies of the methods incorporated by reference in paragraph (b)(4)(iii)(I) of this section may also be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740.

- (1) Bromate shall be measured using the following method: Method 300.1—"Determination of Inorganic Anions in Drinking Water by Ion Chromatography," Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/118, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (2) Chlorite shall be measured using the following methods:
 - (i) Method 300.0—"Determination of Inorganic Anions by Ion Chromatography," Rev. 2.1. The revision is contained in the manual entitled "Methods for the Determination of Inorganic Substances in Environmental Samples," U.S. EPA, August 1993, EPA/600/R-93/100, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

- (ii) Method 300.1—“Determination of Inorganic Anions in Drinking Water by Ion Chromatography,” Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/118, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (3) HAA5 shall be measured using the following methods:
 - (i) Method 552.1—“Determination of Haloacetic Acids and Dalapon in Drinking Water by Ion Exchange Liquid-Solid Extraction and Gas Chromatography with Electron Capture Detection,” Rev. 1.0. The revision is contained in the manual entitled “Methods for the Determination of Organic Compounds in Drinking Water-Supplement II,” U.S. EPA, August 1992, EPA/600/R-92/129, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (ii) Method 552.2—“Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-Liquid Extraction, Derivatization and Gas Chromatography with Electron Capture Detection,” Rev. 1.0. The revision is contained in the manual entitled “Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,” U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

- (iii) Method 6251 B—“Disinfection By-Products: Haloacetic Acids and Trichlorophenol,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (4) TTHM shall be measured using the following methods:

 - (i) Method 502.2—“Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series,” Rev. 2.1. The revision is contained in the manual entitled “Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,” U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (ii) Method 524.2—“Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry,” Rev. 1.0. The revision is contained in the manual entitled “Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,” U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

- (iii) Method 551.1—“Determination of Chlorination Disinfection Byproducts, Chlorinated Solvents, and Halogenated Pesticides/Herbicides in Drinking Water by Liquid-Liquid Extraction and Gas Chromatography with Electron-Capture Detection,” Rev. 1.0. The revision is contained in the manual entitled “Methods for the Determination of Organic Compounds in Drinking Water-Supplement III,” U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (5) Compliance with the chloramine standard can be determined by measuring combined or total chlorine. The following methods shall be used to measure chloramine:

 - (i) ASTM Method D1253-86—“ Standard Test Method for Residual Chlorine in Water,” which is contained in the book entitled “Annual Book of ASTM Standards,” 1996, vol. 11.01, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (ii) Method 4500-Cl D—“Amperometric Titration Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

- (iii) Method 4500-Cl F—“DPD Ferrous Titrimetric Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (iv) Method 4500-Cl G—“DPD Colorimetric Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (v) Method 4500-Cl E—“Low-Level Amperometric Titration Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (vi) Method 4500-Cl I—“Iodometric Electrode Technique,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (6) Compliance with the chlorine standard can be determined by measuring free or total chlorine. The following methods shall be used to measure chlorine:

- (i) ASTM Method D1253-86—“Standard Test Method for Residual Chlorine in Water,” which is contained in the book entitled “Annual Book of ASTM Standards,” 1996, vol. 11.01, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (ii) Method 4500-Cl D—“Amperometric Titration Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (iii) Method 4500-Cl F—“DPD Ferrous Titrimetric Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (iv) Method 4500-Cl G—“DPD Colorimetric Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

- (v) Method 4500-Cl E—“Low-Level Amperometric Titration Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (vi) Method 4500-Cl I—“Iodometric Electrode Technique,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
 - (vii) Method 4500-Cl H—“Syringaldazine (FACTS) Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (7) Chlorine dioxide shall be measured using the following methods:
- (i) Method 4500-ClO₂ D—“DPD Method,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

- (ii) Method 4500-CLO₂E—“Amperometric Method II,” which is contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.
- (5) *Radiological quality.*
- (i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(5)(ii) of this section, meet standards of radiological quality as follows:
 - (A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.
 - (B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.
 - (C) The bottled water 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 an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.
 - (D) The bottled water shall not contain uranium in excess of 30 micrograms per liter of water.

(ii) Analyses conducted to determine compliance with the requirements of paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., may be obtained from the American Public Health Association, 1015 15th St. NW., Washington, DC 20005. Copies of the methods incorporated by reference in this paragraph (b)(5)(ii) may also be examined at the National Archives and Records Administration (NARA), or at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD. For information on the availability of this material at NARA, call 202-741-6030, or go to:
http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(A) Combined radium-226/-228 shall be measured using the following methods:

- (1) Method 7500-Ra B—“Precipitation Method,” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.
- (2) Method 7500-Ra D—“Sequential Precipitation Method,” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

- (B) Gross alpha particle radioactivity shall be measured using the following method:
Method 7110 C—“Coprecipitation Method for Gross Alpha Radioactivity in Drinking Water,” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

- (C) Beta particle and photon radioactivity shall be measured using the following methods:
 - (1) Method 7500-Sr B—“Precipitation Method,” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

 - (2) Method 7500- 3H B—“Liquid Scintillation Spectrometric Method,” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

 - (3) Method 7120 B—“Gamma Spectroscopic Method,” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

- (D) Uranium shall be measured using the following methods:

- (1) Method 7500-U B—“Radiochemical Method” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.
 - (2) Method 7500-U C—“Isotopic Method” which is contained in “Standard Methods for the Examination of Water and Wastewater,” 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.
- (c) *Label statements.* When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in § 130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in § 130.14(a) the following statement(s) shall be used:
- (1) “Contains Excessive Bacteria” if the bottled water fails to meet the requirements of paragraph (b)(2) of this section.
 - (2) “Excessively Turbid”, “Abnormal Color”, and/or “Abnormal Odor” if the bottled water fails to meet the requirements of paragraph (b)(3) (i), (ii), or (iii), respectively, of this section.
 - (3) “Contains Excessive __,” with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., “Contains Excessive Arsenic,” “Contains Excessive Trihalomethanes”) except that “Contains Excessive Chemical Substances” may be used if the bottled water is not mineral water.
 - (4) “Excessively Radioactive” if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

- (d) *Adulteration.* Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section.

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