

applicable sections of parts 101 and 130 of this chapter.

[42 FR 14475, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 61 FR 9325, Mar. 8, 1996; 63 FR 14035, Mar. 24, 1998]

PART 165—BEVERAGES

Subpart A—General Provisions

Sec.

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AUTHORITY: 21 U.S.C. 321, 341, 343, 343-1, 348, 349, 371, 379e.

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Subpart A—General Provisions

§ 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

§ 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 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 “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.* (i) Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in paragraph (b)(2)(ii) of this section, meet the following standards of microbiological quality:

(A) *Total coliform—(1) Multiple-tube fermentation (MTF) 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

(2) *Membrane filter (MF) 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.

(B) *E. coli.* If *E. coli* is present, then the bottled water will be deemed adulterated under paragraph (d) of this section.

(ii) Analyses conducted to determine compliance with paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section and §129.35(a)(3)(i) of this chapter shall be made in accordance with the multiple-tube fermentation (MTF) or the membrane filter (MF) methods described in the applicable sections of “Standard Methods for the Examination of Water and Wastewater,” 21st Ed. (2005), American Public Health Association. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1

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CFR part 51. You may obtain a copy from the American Public Health Association, 800 I St. NW., Washington, DC 20001, 202-777-2742 (APHA). You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, 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.

(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), 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, 202-777-2742 (APHA), 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, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, 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 physical quality:

- (i) The turbidity shall not exceed 5 units.
- (ii) The color shall not exceed 15 units.¹
- (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

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

substances in excess of the following concentrations:

Substance	Concentration in milligrams per liter
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

¹Mineral 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 ex-

cess 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)
Arsenic	0.010
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
Carbon tetrachloride (56–23–5)	0.005
<i>o</i> -Dichlorobenzene (95–50–1)	0.6
<i>p</i> -Dichlorobenzene (106–46–7)	0.075

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Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
1,2-Dichloroethane (107-06-2)	0.005
1,1-Dichloroethylene (75-35-4)	0.007
<i>cis</i> -1,2-Dichloroethylene (156-59-2)	0.07
<i>trans</i> -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)	3×10 ⁻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

Contaminant	Concentration in milligrams per liter
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 variations to the methods listed in paragraphs (b)(4)(iii)(E)(I) through (b)(4)(iii)(E)(I4) 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, 5825 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.

(I) 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)(I)(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](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)(I)(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)(I)(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)(I)(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)(I)(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)(I)(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)(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.

(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)(I)(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)(I)(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.

(14) Arsenic shall be measured using the following methods:

(i) Method 200.8—“Determination of Trace Elements in Waters and Wastes

by Inductively Coupled Plasma-Mass Spectrometry,” Revision 5.4, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.8 is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples—Supplement 1,” EPA/600/R-94/111, May 1994. Copies of this publication are available from the National Technical Information Service (NTIS), PB95-125472, U.S. Department of Commerce, 5825 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 200.9—“Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption,” Revision 2.2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.9 is contained in the manual entitled “Methods for the Determination of Metals in Environmental Samples—Supplement 1,” EPA/600/R-94/111, May 1994. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(14)(i) 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-Chloropro-

pane (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 incor-

porated 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)(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)(I)(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)(I)(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)(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)(I)(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)(I)(i) 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)(I)(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) (HAAs)	0.060
Total Trihalomethanes (TTHM)	0.080
Residual disinfectants	
Chloramine	4.0 (as Cl ₂)
Chlorine	4.0 (as Cl ₂)
Chlorine dioxide	0.8 (as ClO ₂)

(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-Supple-

ment 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 in-

corporation 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)(i)(A) 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 Federal Food, Drug, and Cosmetic Act (the act), or that consists in whole or in part of any filthy, putrid, or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) 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. If *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.

[60 FR 57124, Nov. 13, 1995; 60 FR 66495, Dec. 22, 1995, as amended at 61 FR 13264, Mar. 26, 1996; 61 FR 14480, Apr. 2, 1996; 63 FR 25769, May 11, 1998; 66 FR 16865, Mar. 28, 2001; 66 FR 17359, Mar. 30, 2001; 66 FR 35373, July 5, 2001; 66 FR 56035, Nov. 6, 2001; 58 FR 15355, Mar. 31, 2003; 68 FR 9881, Mar. 3, 2003; 70 FR 33700, June 9, 2005; 74 FR 25665, May 29, 2009]

PART 166—MARGARINE

Subpart A—General Provisions

Sec.

166.40 Labeling of margarine.

Subpart B—Requirements for Specific Standardized Margarine

166.110 Margarine.

AUTHORITY: 21 U.S.C. 321, 341, 343, 347, 348, 371, 379e.

Subpart A—General Provisions

§ 166.40 Labeling of margarine.

The Federal Food, Drug, and Cosmetic Act was amended by Pub. L. 459, 81st Congress (64 Stat. 20) on colored oleomargarine or margarine by adding thereto a new section numbered 407. Among other things, this section requires that there appear on the label of the package the word “oleomargarine” or “margarine” in type or lettering at least as large as any other type or lettering on the label, and a full and accurate statement of all the ingredients contained in such oleomargarine or margarine. It provides that these requirements “shall be in addition to and not in lieu of any of the other requirements of this Act”.

(a) Under section 403(g) of the Federal Food, Drug, and Cosmetic Act, any article that is represented as or purports to be oleomargarine or margarine must conform to the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act (Subpart B of this part), and its label must bear the name “oleomargarine” or “margarine”.

(b) The identity standard for oleomargarine or margarine applies to both the uncolored and the colored article.

(c) In considering the requirement that the word “oleomargarine” or “margarine” be in type or lettering at least as large as any other type or lettering on the label, it must be borne in mind that at least three factors are involved—the height of each letter, the area occupied by each letter as measured by a closely fitting rectangle drawn around it, and the boldness of letters or breadth of the lines forming the letters. The type or lettering used should meet the following tests:

(1) The height of each letter in the word “oleomargarine” or “margarine” should equal or exceed the height of any other letter elsewhere on the label.

(2) The area of the closely fitting rectangle with respect to any of the letters in the word “oleomargarine” or “margarine” should equal or exceed the area of such rectangle applied to