



STATE OF LOUISIANA
DEPARTMENT OF HEALTH AND HOSPITALS



Dear Prospective Bottled Water Importer:

I am pleased to provide you with the attached documents as a guideline to the steps necessary in order to obtain a Certificate of Registration as a bottled-water distributor in the state of Louisiana. Please read the following information carefully, and if you have any questions immediately after reviewing it, please contact my office.

1. Required Items for Approval of New Water Sources, Products, and/or Bottling Plants: Your first step in obtaining a Certificate of Registration for your water product is to ensure that your water source will be approved for this use. Below you will find several different scenarios for various permutations of new products, bottling plants, or sources. Please review the following information to determine which of these scenarios best characterizes your activities.

For a new product [that has never previously been registered] and/or a new facility, we require the following documentation: a hydrogeological report prepared by a professional geologist detailing the regional and local geology, as well as the development of catchment facilities; a recent set of test results documenting that the source water is being monitored for the contaminants specified in the attached **Testing Requirements for Bottled Water – Product and Source**, a recent set of test results verifying that product water is compliant with the standard of identity found in **21 CFR 165.110**, a copy of the most recent certificate/inspection/license issued by the state or local regulatory authority having jurisdiction over the bottling plant, a completed FD-9(N) Application for a New Product Registration, specimen labels for each distinct product, and the appropriate fee of \$20 per product up to a maximum of \$200 per DBA.

New products will be issued a Certificate of Registration once all documentation has been received and reviewed by the Sanitarian Program Manager for Bottled Water. New facilities may be issued a Certificate of Registration at the discretion of the management of the corporate owner of the facility. **Note that it is not our standard practice to issue CoR documents to each facility manufacturing a particular product; the CoR is intended to be issued once to the corporate owner of the facility or facilities that manufacture said product.** However, we will accommodate corporate policies that may require each plant to have a certificate.

For a new source utilized by an existing product and an approved facility, we require the following information: a hydrogeological report as described below and a recent set of test results documenting that the source water is being monitored for the contaminants specified in the attached **Testing Requirements for Bottled Water – Product and Source**. New sources will be issued an approval letter by the Sanitarian Program Manager for Bottled Water.

For new facilities producing a previously-registered product and an approved source, we require the following documentation: a copy of the most recent certificate/inspection/license issued by the state or local regulatory authority having jurisdiction over the bottling plant and test results verifying that the product water (**from this specific plant**) is compliant with the standard of identity found in 21 CFR 165.110. As indicated above, new facilities may be issued a Certificate of Registration if

corporate policy requires it; otherwise, a new facility will receive an approval letter from the Sanitarian Program Manager for Bottled Water.

Submission of Hydrogeological Report on Source to Program Manager: The report is to be submitted to the Sanitarian Program Manager for Bottled Water for review at (225) 342-7672 [fax] or regular mail at Bin # 14, P.O. Box 4489, Baton Rouge, LA 70821-4489. The report must include the following items (at a minimum) and it must be signed and certified by a credentialed professional geologist or hydrogeologist:

- a) a report on the regional geology and the specific site geology of the source area, including a description of the vertical and horizontal extent of the source aquifer using existing data;
- b) a report detailing the development of the source, the method of construction including spring design, well installation, surface catchment and intake structures, and transmission facilities as appropriate;
- c) a watershed survey of the recharge area or zone of influence of subject source that identifies and evaluates actual and potential sources of contamination;
- d) and, based on the findings of Section (c) above, a plan for special monitoring of any significant contaminant source and for taking restrictive preventive or corrective measures as appropriate to protect the source and product water.

2. Product Registration: Your non-bulk products (any sizes below 3 gallons) must be registered with this office. Therefore, you must submit proofs or specimen copies of labels containing all of the basic information provided in and meeting the criteria outlined in 21 CFR 101 *et seq.* (not provided—this document is available from the Food and Drug Administration). Labels must be submitted to the Program Manager for Product Registration, currently Brian R. Warren, at (225) 342-7672 [fax] or regular mail at Bin # 14, P.O. Box 4489, Baton Rouge, LA 70821-4489. Assemble a registration packet consisting of the attached **FD-9(N) Application for a New Product Registration Form**, a check or money order for \$20 per distinct product, and specimens or proofs of each label.

Clarification of “Distinct Product” and What It Means in the Bottled Water Industry: An additional note on registration: the term “distinct product” as it applies to bottled water may mean several things. If your firm will manufacture a distilled water product and a spring water product, these are two distinct products. However, if your firm will produce a Brand X distilled water and a Brand Y distilled water, these are also two distinct products. So, the rule of thumb to follow here is this: if the water conforms to a different standard of identity as specified in **21 CFR 165.110 (Bottled water)**, it is a distinct product, and if you manufacture said product under different brand names or private labels, each of those constitutes a separate product as well. You **must** register each product that your firm manufactures (meaning that it must be listed on the FD-9 form or an attached document and a label must be provided), but the registration fee is capped at 10 products or \$200. Please note that multiple sizes (12 oz., 16 oz., 1 gallon) of the same product are **not** considered distinct products and may be registered as a single product.

3. Source And Product Water Monitoring: Once construction is complete on your well, if you are relying on a private water supply, you will need to perform tests on a sample taken from your sample tap. The required testing and monitoring regimen is outlined in the attached **Testing Requirements for Bottled Water – Source and Product** document. Public water sources may submit documents verifying that the source is fully compliant with the National Primary Drinking Water Regulations (40 CFR 141—not provided, this document may be obtained from the Environmental Protection Agency).

Once a source sample is collected (according to the guidelines of and using the sample container provided by the testing laboratory), you may submit the sample to a NELAP- and/or state-certified laboratory for drinking water chemistry for the performance of annual, quadrennial, and triennial analysis for chemical, physical, and radiological contaminants and/or a NELAP- or state-certified laboratory for drinking water microbiology for the coliform analysis. An in-house laboratory may conduct the routine weekly microbiological testing, but annual tests must be performed by a NELAP- or state-certified laboratory for drinking water chemistry. Contact the NELAC Institute for a current listing of NELAP-certified laboratories in your area and your state environmental quality or public health agency (depending on which agency oversees laboratory certification) for a list of state-certified laboratories for drinking water chemistry and microbiology.

Attachments: PLEASE FIND THE FOLLOWING DOCUMENTS ATTACHED TO THIS GUIDE

FD-9(N) APPLICATION FOR A NEW PRODUCT REGISTRATION FORM
21 CFR 165.110 STANDARD OF IDENTITY FOR BOTTLED WATER
TESTING REQUIREMENTS FOR BOTTLED WATER – SOURCE AND PRODUCT



NEW COMPANY INITIAL APPLICATION

Check the appropriate product type below:

FOOD DRUG COSMETIC PROPHYLACTIC SEAFOOD MILK/DAIRY

Date		Registration No. (For Office Use Only)	
Company Contact Person	Taxpayer ID	Telephone No.	Fax No.
Name of Manufacturer, Distributor, Packer, Processor, or Importer (exactly as it appears on the label)			
Address	City	State	ZIP Code
If this is a private-label/copacked product, list the name of the actual manufacturer here			
Address	City	State	ZIP Code
Name of firm submitting application			
Address (Mailing)	City	State	ZIP Code
Signature of Executive Officer, Proprietor, Partner, or Agent for Service of Process		Title	

APPLICATION IS HEREBY MADE BY THE ABOVE-REFERENCED INDIVIDUALS/COMPANIES TO SELL OR OTHERWISE DISTRIBUTE PACKAGED FOOD, DRUG, COSMETIC, OR PROPHYLACTIC DEVICES IN THE STATE OF LOUISIANA, IN ACCORDANCE WITH LSA R.S. 40: 627 *ET SEQ.* APPLICATION IS BEING MADE IN THE NAME OF THE RESPONSIBLE PARTY FOR THE AFOREMENTIONED PRODUCTS, WHOSE NAME AND ADDRESS APPEAR ON THE LABELS, AS REQUIRED BY STATE AND FEDERAL LAW. BY SIGNING IN THE SPACE PROVIDED, I ACKNOWLEDGE THAT I HAVE ATTACHED A CATALOG LISTING OF ALL PRODUCTS I INTEND TO DISTRIBUTE IN LOUISIANA ALONG WITH PROOFS OR SPECIMEN LABELS FOR ALL SUCH PRODUCTS IN PAPER OR ELECTRONIC FORM, AS REQUIRED BY LOUISIANA LAW.

REGISTRATION FEE: THE FEE FOR PRODUCT REGISTRATION IS \$20 PER PRODUCT UP TO A MAXIMUM PER DBA OF \$200. MULTIPLY \$20 BY THE NUMBER OF PRODUCTS YOU INTEND TO REGISTER OR 10 IF THE NUMBER IS GREATER THAN 10, AND ENTER THAT NUMBER IN THE LINE TO THE RIGHT. NOTE THAT IF YOU ARE REGISTERING MORE THAN ONE DBA, YOU MUST USE MORE THAN ONE FD-9(N).
MAKE ALL CHECKS AND MONEY ORDERS PAYABLE TO DHH.

Total number of products to register:

Fee attached _____

List below the names and addresses of three brokers, warehousemen, or distributors who will be handling your products in the state. If you do not currently have any distributors, indicate "SELF-DISTRIBUTION" in the first space below.

1) _____ 2) _____ 3) _____

FOR OFFICE USE ONLY

REGISTRATION YEAR _____ CHECK NUMBER _____ PROCESSED BY _____
 SHEET NUMBER _____ CHECK DATE _____ CERTIFICATE TYPE _____
 SHEET DATE _____ REGISTRATION NUMBER _____

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 Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC), 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 Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC), 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 Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition’s Library, 200 C St., SW., Washington, DC), 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

(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

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

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(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 Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington DC, or the Center for Food Safety and Applied Nutrition's Library, 200 C St. NW., Washington DC. 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)
Antimony006.
Barium	2.
Beryllium	0.004.

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Contaminant	Concentration in milligrams per liter (or as specified)
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
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

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
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)(I) through (b)(4)(iii)(E)(J3) 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 Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(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 Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(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 Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(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)(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.

(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 Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(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)(I)(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)(I)(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 Absorp-

tion 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 Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(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)(I)(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)(I)(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)(I) 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 De-

termination 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 Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(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 Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(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.

(I) 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)(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)(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) (HAA5)	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 Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740. 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 Office of the FEDERAL REGISTER, 800 North Capital St. NW., suite 700, Washington, DC, or at the

Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD.

(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.

[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]

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

Testing Requirements for Bottled Water – Source and Product

This document represents a careful reading of the relevant state and federal statutory requirements for testing of source and product water by bottled-water manufacturers. The testing delineated below represents the minimum legal standard that all bottlers either distributing water from or into the state of Louisiana must follow. Results from in-state manufacturers must be submitted to the Bottled Water Program Manager of the Food and Drug Unit on the schedule outlined in the Notice to Bottled Water Manufacturers dated October 12, 2006. Questions regarding this information may be directed to the FDU Bottled Water Program Manager at (225) 342-7517.

Class	Analyte	DHH Frequency		DHH SOQ	Source
		Source Water	Product Water		
Microbiological				cfu/100mL	
CFR 165.110	Coliform bacteria	1/week ¹	1/week	2.2 or 4 ¹¹	735(B), 736(A).1
Primary Inorganics		Source Water	Product Water	mg/L	
CFR 165.110	Antimony	1/year ²	1/year	0.006	735(C)
CFR 165.110	Arsenic	1/year ¹	1/year	0.01	735(B), 736(A).2
CFR 165.110	Barium	1/year ¹	1/year	2	735(B), 736(A).2
CFR 165.110	Beryllium	1/year ²	1/year	0.004	735(C)
CFR 165.110	Cadmium	1/year ¹	1/year	0.005	735(B), 736(A).2
CFR 165.110	Chromium	1/year ¹	1/year	0.1	735(B), 736(A).2
CFR 165.110	Cyanide	1/year ²	1/year	0.02	735(C)
CFR 165.110	Fluoride	1/year ¹	1/year	1.6/1.0 ⁶	735(B), 736(A).2
CFR 165.110	Lead	1/year ¹	1/year	0.005	735(B), 736(A).2
CFR 165.110	Mercury	1/year ¹	1/year	0.002	735(B), 736(A).2
CFR 165.110	Nickel	1/year ²	1/year	0.1	735(C)
CFR 165.110	Nitrate (as N)	1/year ¹	1/year	10	735(B), 736(A).2
CFR 165.110	Nitrite (as N)	1/year ²	1/year	1	
CFR 165.110	Total Nitrate and Nitrite (as N)	1/year ²	1/year	10	
CFR 165.110	Selenium	1/year ¹	1/year	0.05	735(B),

					736(A).2
CFR 165.110	Thallium	1/year ²	1/year	0.002	735(C)
Secondary Inorganics				mg/L	
CFR 165.110	Aluminum	1/year ²	1/year	0.2	735(C)
CFR 165.110	Chloride	1/year ¹	1/year	250 ⁵	735(B), 736(A).2
CFR 165.110	Color	1/year ¹	1/year	15 (units) ⁵	735(B), 736(A).2
CFR 165.110	Copper	1/year ¹	1/year	1	735(B), 736(A).2
CFR 165.110	Iron	1/year ¹	1/year	0.3 ⁵	735(B), 736(A).2
CFR 165.110	Manganese	1/year ¹	1/year	0.05 ⁵	735(B), 736(A).2
CFR 165.110	Odor	1/year ¹	1/year	See note ⁸	735(B), 736(A).2
USP XXIII	pH	1/year ¹	1/year	6.5 – 8.5 ⁷	735(B), 736(A).2
CFR 165.110	Silver	1/year ¹	1/year	0.1	735(B). 736(A).2
CFR 165.110	Sulphate	1/year ¹	1/year	250 ⁵	735(B), 736(A).2
CFR 165.110	Total Dissolved Solids (TDS)	1/year ¹	1/year	500 ⁵	735(B), 736(A).2
CFR 165.110	Turbidity	1/year ¹	1/year	5 (units)	735(B), 736(A).2
CFR 165.110	Zinc	1/year ¹	1/year	5 ⁵	735(B), 736(A).2
Volatile Organic Compounds				mg/L	
CFR 165.110	1,1,1-Trichloroethane	1/year ¹	1/year	0.2	735(B), 736(A).2
CFR 165.110	1,1,2-Trichloroethane	1/year ²	1/year	0.005	735(C)
CFR 165.110	1,1-Dichloroethylene	1/year ¹	1/year	0.007	735(B), 736(A).2
CFR 165.110	1,2,4-Trichlorobenzene	1/year ²	1/year	0.07	
CFR 165.110	1,2-Dichloroethane	1/year ¹	1/year	0.005	735(B), 736(A).2
CFR 165.110	1,2-Dichloropropane	1/year ²	1/year	0.005	735(C)
CFR 165.110	Benzene	1/year ¹	1/year	0.005	735(B), 736(A).2
CFR 165.110	Carbon tetrachloride	1/year ¹	1/year	0.005	735(B), 736(A).2
CFR 165.110	<i>cis</i> -1,2-Dichloroethylene	1/year ²	1/year	0.07	735(C)

CFR 165.110	Dichloromethane (Methylene chloride)	1/year ²	1/year	0.005	735(C)
CFR 165.110	Ethylbenzene	1/year ²	1/year	0.7	735(C)
CFR 165.110	Monochlorobenzene (chlorobenzene)	1/year ²	1/year	0.1	735(C)
CFR 165.110	<i>ortho</i> -Dichlorobenzene	1/year ²	1/year	0.6	
CFR 165.110	<i>para</i> -Dichlorobenzene	1/year ¹	1/year	0.075	735(B), 736(A).2
CFR 165.110	Styrene	1/year ²	1/year	0.1	
CFR 165.110	Tetrachloroethylene	1/year ²	1/year	0.005	735(C)
CFR 165.110	Toluene	1/year ²	1/year	1	735(C)
CFR 165.110	<i>trans</i> -1,2-Dichloroethylene	1/year ²	1/year	0.1	735(C)
CFR 165.110	Trichloroethylene	1/year ¹	1/year	0.005	735(B), 736(A).2
CFR 165.110	Vinyl chloride	1/year ¹	1/year	0.002	735(B), 736(A).2
CFR 165.110	Xylenes (total)	1/year ²	1/year	10	735(C)
Synthetic Organic Compounds				mg/L	
CFR 165.110	Alachlor	1/year ²	1/year	0.002	735(C)
CFR 165.110	Atrazine	1/year ²	1/year	0.003	735(C)
CFR 165.110	Benzo(a)pyrene	1/year ²	1/year	0.0002	735(C)
CFR 165.110	Carbofuran	1/year ²	1/year	0.04	735(C)
CFR 165.110	Chlordane	1/year ²	1/year	0.002	735(C)
CFR 165.110	Dalapon	1/year ²	1/year	0.2	735(C)
CFR 165.110	Dibromochloropropane (DBCP)	1/year ²	1/year	0.0002	735(C)
CFR 165.110	Di(2-ethylhexyl)adipate	1/year ²	1/year	0.4	
CFR 141.61	Di(2-ethylhexyl)phthalate	1/4 years ¹	1/year	0.006 ¹²	735(C), 736(A).2
CFR 165.110	Dinoseb	1/year ²	1/year	0.007	
CFR 165.110	Diquat	1/year ²	1/3 years ^{2,13}	0.002	735(C)
CFR 165.110	2,4-Dichlorophenoxyacetic acid	1/year ¹	1/year	0.07	735(B), 736(A).2
CFR 165.110	Endothall	1/year ²	1/3 years ^{2,13}	0.1	735(C)
CFR 165.110	Endrin	1/year ¹	1/year	0.002	735(B), 736(A).2
CFR 165.110	Ethylene dibromide (EDB)	1/year ²	1/year ²	0.00005	735(C)
CFR 165.110	Glyphosate	1/year ²	1/3 years ^{2,13}	0.7	735(C)
CFR 165.110	Heptachlor	1/year ²	1/year ²	0.0004	735(C)
CFR 165.110	Heptachlor epoxide	1/year ²	1/year ²	0.0002	735(C)
CFR 165.110	Hexachlorobenzene	1/year ²	1/year ²	0.001	735(C)
CFR 165.110	Hexachlorocyclopentadiene	1/year ²	1/year ²	0.05	735(C)
CFR 165.110	Lindane (γ -HCH)	1/year ¹	1/year	0.0002	735(B),

					736(A).2
CFR 165.110	Methoxychlor	1/year ¹	1/year	0.04	735(B), 736(A).2
CFR 165.110	Oxamyl (vydate)	1/year ²	1/year	0.2	735(C)
CFR 165.110	Picloram	1/year ²	1/year ²	0.5	735(C)
CFR 165.110	Polychlorinated biphenyls (PCBs)	1/year ²	1/year ²	0.0005	735(C)
CFR 165.110	Pentachlorophenol	1/year ²	1/year ²	0.001	735(C)
CFR 165.110	Simazine	1/year ²	1/year	0.004	
CFR 165.110	Toxaphene	1/year ¹	1/year	0.003	735(B), 736(A).2
CFR 165.110	Total Recoverable Phenolics	1/year ²	1/year ²	0.001	
CFR 165.110	2,3,7,8-TCDD (dioxin)	1/year ²	1/3 years ^{2,13}	3x10 ⁻⁸	735(C)
CFR 165.110	2,4,5-TP (Silvex)	1/year ¹	1/year	0.05	735(B), 735(C), 736(A).2
Disinfectants and Disinfectant Byproducts				mg/L	
CFR 165.110	Total trihalomethanes ⁴	1/year ¹	1/year	0.08	735(B), 736(A).2
	Bromodichloromethane			See note ⁴	
	Chlorodibromomethane			See note ⁴	
	Chloroform			See note ⁴	
	Bromoform			See note ⁴	
CFR 165.110	Haloacetic acids five (HAA5)	1/year ²	1/year ²	0.06	735(D)
CFR 165.110	Bromate	1/year ¹	1/year ¹⁴	0.01	
CFR 165.110	Chlorite	1/year ¹	1/year ¹⁵	1	
CFR 165.110	Chlorine	1/year ¹	1/year ¹⁶	4	
CFR 165.110	Chloramines	1/year ¹	1/year ¹⁷	4	
CFR 165.110	Chlorine dioxide	1/year ¹	1/year ¹⁵	0.8	
Radiological		Source Water	Product Water	mg/L	
CFR 165.110	Gross α	1/4 years ¹	1/year	15 pCi/L	735(B), 736(A).2
CFR 165.110	Gross β	1/4 years ¹	1/year	50 pCi/L ¹⁰	735(B), 736(A).2
CFR 165.110	Combined radium 226/228	1/4 years ¹	1/year	5 pCi/L	735(B), 736(A).2
CFR 165.110	Ra-226	1/4 years ⁹	1/year		735(B), 736(A).2
CFR 165.110	Ra-228	1/4 years ⁹	1/year		735(B), 736(A).2
CFR 165.110	Uranium	1/4years ¹	1/year	0.03	735(B), 736(A).2

¹ Test is not required if the source is a listed public water system and the operator posts or provides a document from the PWS stating that it is in compliance with 40 CFR requirements.

² Test is not required if the source is a listed public water system and the operator posts or provides a document from the PWS stating that it is in compliance with 40 CFR requirements. Testing frequency is mandated by federal regulations (40 CFR or 21 CFR 165.110).

³ Test is required only for bottlers using chlorination or chlorinated public water as a source.

⁴ No MCL/SOQ exists for individual trihalomethanes. The TTHM MCL was changed by rulemaking in 2001 to 0.08 from the original 0.01 mg/L codified in LSA R.S. 40: 740(A). A bottler may be exempted from testing trihalomethanes if only UV is employed as a method of disinfection.

⁵ Mineral water is exempt from the allowable levels. These exemptions are aesthetically-based allowable levels and do not address a specific health concern.

⁶ FDA SOQ for fluoride varies from 0.8 to 2.4 mg/L based upon whether fluoride is naturally occurring or added artificially and the annual average of maximum daily air temperatures. Climatic conditions in the state of Louisiana dictate that MCL values should be 1.6 mg/L for naturally-occurring fluoride and 1.0 mg/L for added fluoride. Bottled water manufactured outside of the U.S. has an MCL of 1.4 mg/L for naturally-occurring fluoride and 0.8 mg/L for artificially-added fluoride. For other areas, please see 21 CFR 165.110 and consult local climatic databases.

⁷ USP XXIII requires purified water to have a pH of 5.0 – 7.0. The guidelines for source water and other product waters is 6.5 – 8.5.

⁸ Odor shall not exceed threshold odor No. 3.

⁹ No MCL or SOQ exists for individual isotopes of radium. State statutory and CFR requirements specify a gross α MCL of 15 pCi/L, but state law doesn't mandate testing for radium levels unless gross α exceeds 5 pCi/L. However, 21 CFR 165.110 mandates annual radium testing, irrespective of gross α levels.

¹⁰ This is the MCL listed in LSA R.S. 40: 740(A). This is a unit measure of radioactivity and it is derived from the EPA 2000 Radionuclides Rule, which characterizes 50 pCi/L gross β radioactivity as a screening level for water systems classified by the state as "vulnerable." It is not directly equivalent to the stated MCLs given in 40 CFR 141.66 and 21 CFR 165.110 of 4 mrem/year, because the rem is a unit of absorbed dose. In order to assume or achieve compliance with federal regulatory requirements, certain assumptions must be made regarding consumption and absorption of radioactivity-producing isotopes.

Specifically, a level of gross β radioactivity in excess of 8 pCi/L requires that the bottler test to see whether the isotope causing the radioactivity is Strontium-90. This is because strontium-induced radioactivity in excess of this level is assumed to result in an excess of a 4-mrem absorbed dose in humans on the basis of consumption of 2L of radioactive water per day. State law further mandates that any gross β level over 50 pCi/L requires that the bottler test for specific levels of tritium and other artificial radionuclides. The testing laboratory will document any radioactivity levels that produce an exceedance of the EPA- and FDA-specified MCL of a 4-mrem absorbed dose per year.

¹¹2.2 cfu/100mL for multiple-tube fermentation method or 4 cfu/100mL for membrane filter method of testing

¹²EPA MCL is incorporated by reference in LSA R.S. 40: 735(C) and 736(A).2. No FDA SOQ exists for this contaminant.

¹³According to IBWA, FDA requirements include an initial round of testing for four consecutive quarters for each type of product water. If the contaminant is not detected, product may be tested once every three years; otherwise, monitoring for four additional consecutive quarters must occur. (This is a translation of EPA 40 CFR water system testing requirements to the bottled water conventions of source and product water testing.)

¹⁴Testing is required if the bottler uses ozone for disinfection or if source testing detects this contaminant at or above listed MCL.

¹⁵Testing is required if the bottler uses chlorine dioxide for disinfection or if source testing detects this contaminant at or above listed MCL.

¹⁶Testing is required if the bottler uses chlorine for disinfection or if source testing detects this contaminant at or above listed MCL.

¹⁷Testing is required if the bottler uses chloramines for disinfection or if source testing detects this contaminant at or above listed MCL.