

*Contains Nonbinding Recommendations*

# Guidance for Industry

## Bottled Water: Residual Disinfectants and Disinfection Byproducts Small Entity Compliance Guide

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*Office of Food Safety*

*Division of Plant and Dairy Food Safety (HFS-317)*

*Center for Food Safety and Applied Nutrition*

*Food and Drug Administration*

*5100 Paint Branch Parkway*

*College Park, MD 20740*

*(Tel) 301-436-1700*

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
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# **Guidance for Industry<sup>1</sup>**

## **Bottled Water: Residual Disinfectants and Disinfection Byproducts Small Entity Compliance Guide**

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### **I. Introduction**

On March 28, 2001, FDA published a direct final rule (66 FR 16858) that amended its bottled water quality standard regulations by establishing allowable levels for the residual disinfectants chloramine, chlorine, and chlorine dioxide and for three types of disinfection byproducts (DBPs), bromate, chlorite, and haloacetic acids (HAA5). The rule also revised the existing allowable level for the DBP total trihalomethanes (TTHM). FDA also revised, for the three residual disinfectants and four types of DBPs only, the monitoring requirement for source water found in the current good manufacturing practice (CGMP) regulations for bottled water. As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for these residual disinfectants and DBPs at least once each year under the CGMP regulations for bottled water. Bottled water manufacturers also are required to monitor for these contaminants at least once each year in their source water, unless the bottlers meet the criteria for source water testing exemptions under the CGMP regulations. On July 5, 2001, FDA issued a technical amendment to correct an editorial error and confirmed the effective date of January 1, 2002, for the direct final rule (66 FR 35373).

FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the legal requirements of the March 28, 2001 direct final rule set forth in 21 CFR 129 and 165 concerning the contaminants residual disinfectants and DBPs. These regulations are binding and have the full force and effect of the law.

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<sup>1</sup> This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## **II. Background**

Under section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act, not later than 180 days before the effective date of a National Primary Drinking Water Regulation issued by the Environmental Protection Agency (EPA) for a contaminant under section 1412 of the Safe Drinking Water Act, FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems, but not in water used for bottled water.

In the Federal Register of December 16, 1998 (63 FR 69390), the EPA published the Stage 1 Disinfection Byproducts Rule establishing maximum contaminant levels for the DBPs bromate, chlorite, HAA5, and TTHM. EPA also established maximum residual disinfectant levels for the chlorine-based disinfectants chlorine, chloramine, and chlorine dioxide. EPA took this action, in part, because some disinfectants and DBPs have been shown to cause cancer and reproductive effects in lab animals and suggested bladder cancer and reproductive effects in humans.

In response to this EPA rulemaking, FDA published the March 28, 2001 direct final rule. This direct final rule ensures that the minimum quality of bottled water, as affected by the DBPs bromate, chlorite, HAA5, and TTHM, and the residual disinfectants chloramine, chlorine, and chlorine dioxide, remains comparable with the quality of public drinking water that meets EPA's standards.

## **III. Questions and Answers**

1. What is the allowable level established by FDA for bromate in bottled water?

The allowable level established by FDA for bromate in bottled water is 0.010 milligram per liter (mg/l) (21 CFR 165.110(b)(4)(H)).

2. What analytical method is used for determining compliance with the allowable level for bromate in bottled water?

The analytical method used for determining compliance with the allowable level for bromate in bottled water is as follows:

- 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 (21 CFR 165.110(b)(4)(I)(1)).

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3. What is the allowable level established by FDA for chlorite in bottled water?

The allowable level established by FDA for chlorite in bottled water is 1.0 mg/l (21 CFR 165.110(b)(4)(H)).

4. What analytical methods are used for determining compliance with the allowable level for chlorite in bottled water?

The analytical methods used for determining compliance with the allowable level for chlorite in bottled water are as follows:

- Method 300.0—“Determination of Inorganic Anions by Ion Chromatography,” Rev. 2.1, 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 (21 CFR 165.110(b)(4)(I)(2)(i)), and
- 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 (21 CFR 165.110(b)(4)(I)(2)(ii)).

5. What is the allowable level established by FDA for HAA5 in bottled water?

The allowable level established by FDA for HAA5 in bottled water is 0.060 mg/l (21 CFR 165.110(b)(4)(H)).

6. What analytical methods are used for determining compliance with the allowable level for HAA5 in bottled water?

The analytical methods used for determining compliance with the allowable level for HAA5 in bottled water are as follows:

- 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, which 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 (21 CFR 165.110(b)(4)(I)(3)(i)).
- 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, which 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 (21 CFR 165.110(b)(4)(I)(3)(ii)).
- Method 6251 B—“Disinfection By-Products: Haloacetic Acids and Trichlorophenol,” contained in the book entitled “Standard Methods for the

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Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(3)(iii)).

7. What is the allowable level established by FDA for TTHM in bottled water?

The allowable level established by FDA for TTHM in bottled water is 0.080 mg/l (21 CFR 165.110(b)(4)(H)).

8. What analytical methods are used for determining compliance with the allowable level for TTHM in bottled water?

The analytical methods used for determining compliance with the allowable level for TTHM in bottled water are as follows:

- 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, 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 (21 CFR 165.110(b)(4)(I)(4)(i)).
- Method 524.2—“Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry,” Rev. 1.0, 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 (21 CFR 165.110(b)(4)(I)(4)(ii)).
- 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, 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 (21 CFR 165.110(b)(4)(I)(4)(iii)).

9. What is the allowable level established by FDA for chloramine in bottled water?

The allowable level established by FDA for chloramine in bottled water is 4.0 (as Cl<sub>2</sub>) (21 CFR 165.110(b)(4)(H)).

10. What analytical methods are used for determining compliance with the allowable level for chloramine in bottled water?

The analytical methods used for determining compliance with the allowable level for chloramine in bottled water are as follows:

- ASTM Method D1253-86—“Standard Test Method for Residual Chlorine in Water,” contained in the book entitled “Annual Book of ASTM Standards,” 1996, vol. 11.01 (21 CFR 165.110(b)(4)(I)(5)(i)).

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- Method 4500-C1 D—“Amperometric Titration Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(5)(ii)).
- Method 4500-C1 F—“DPD Ferrous Titrimetric Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(5)(iii)).
- Method 4500-C1 G—“DPD Colorimetric Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(5)(iv)).
- Method 4500-C1 E—“Low-Level Amperometric Titration Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19<sup>th</sup> Ed. (21 CFR 165.110(b)(4)(I)(5)(v)).
- Method 4500-C1 I—“Iodometric Electrode Technique,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(5)(vi)).

11. What is the allowable level established by FDA for chlorine in bottled water?

The allowable level established by FDA for chlorine in bottled water is 4.0 mg/l (as Cl<sub>2</sub>) (21 CFR 165.110(b)(4)(H)).

12. What analytical methods are used for determining compliance with the allowable level for chlorine in bottled water?

The analytical methods used for determining compliance with the allowable level for chlorine in bottled water are as follows:

- ASTM Method D1253-86—“Standard Test Method for Residual Chlorine in Water,” contained in the book entitled “Annual Book of ASTM Standards,” 1996, vol. 11.01 (21 CFR 165.110(b)(4)(I)(6)(i)).
- Method 4500-C1 D—“Amperometric Titration Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(6)(ii)).
- Method 4500-C1 F—“DPD Ferrous Titrimetric Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(6)(iii)).
- Method 4500-C1 G—“DPD Colorimetric Method, contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(6)(iv)).
- Method 4500-C1 E—“Low-Level Amperometric Titration Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19<sup>th</sup> Ed. (21 CFR 165.110(b)(4)(I)(6)(v)).
- Method 4500-C1 I—“Iodometric Electrode Technique,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19th Ed. (21 CFR 165.110(b)(4)(I)(6)(vi)).

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- Method 4500-Cl H—“Syringaldazine (FACTS) Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19<sup>th</sup> Ed. (21 CFR 165.110(b)(4)(I)(6)(vii)).

13. What is the allowable level established by FDA for chlorine dioxide in bottled water?

The allowable level established by FDA for chlorine dioxide in bottled water is 0.8 mg/l (as ClO<sub>2</sub>) (21 CFR 165.110(b)(4)(H)).

14. What analytical methods are used for determining compliance with the allowable level for chlorine dioxide in bottled water?

The analytical methods used for determining compliance with the allowable level for chlorine dioxide in bottled water are as follows:

- Method 4500-ClO<sub>2</sub> D—“DPD Method,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19<sup>th</sup> Ed. (21 CFR 165.110(b)(4)(I)(7)(i)).
- Method 4500-ClO<sub>2</sub> E—“Amperometric Method II,” contained in the book entitled “Standard Methods for the Examination of Water and Wastewater,” 19<sup>th</sup> Ed. (21 CFR 165.110(b)(4)(I)(7)(ii)).

15. Are bottled water firms that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone required to test for the residual disinfectants chloramine, chlorine, and chlorine dioxide and the DBPs bromate, chlorite, HAA5, and TTHM?

No. (21 CFR 129.35(a)(4)(iii)).

16. Are bottled water firms that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone required to test their source water for residual disinfectants (chloramine, chlorine, and chlorine dioxide) and DBPs (bromate, chlorite, HAA5, and TTHM) that are likely to result from such treatment?

Yes, in some cases. Bottled water firms that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants (chloramine, chlorine, and chlorine dioxide) and DBPs (bromate, chlorite, HAA5, and TTHM) that are likely to result from such treatment (21 CFR 129.35(a)(4)(iii)).