

Contains Nonbinding Recommendations

Guidance for Industry

Bottled Water: Arsenic Small Entity Compliance Guide

*Additional copies are available from:
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
<http://www.cfsan.fda.gov/guidance.html>*

You may submit written or electronic comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

April 2009

FDA-2009-D-0196

GDC

Contains Nonbinding Recommendations

Table of Contents

I. Introduction

II. Background

III. Questions and Answers

Contains Nonbinding Recommendations

Guidance for Industry¹

Bottled Water: Arsenic Small Entity Compliance Guide

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

On June 9, 2005, FDA published a final rule that amended its bottled water quality standard regulations by revising the existing allowable level for the contaminant arsenic. As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for arsenic at least once each year under the current good manufacturing practice (CGMP) regulations for bottled water (21 CFR part 129). Bottled water manufacturers are also required to monitor their source water for arsenic as often as necessary, but at least once each year unless they meet the criteria for the source water monitoring exemptions under the CGMP regulations. This final rule became effective on January 23, 2006 (70 FR 33694).

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 June 9, 2006 final rule set forth in 21 CFR part 165 concerning the contaminant arsenic. These regulations are binding and have the full force and effect of law.

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.

¹ 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.

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 drinking water.

In the Federal Register of January 22, 2001 (66 FR 6976), EPA published a final rule establishing a maximum contaminant level for arsenic in public drinking water. EPA took this action, in part, because studies have shown long-term exposure to inorganic arsenic in drinking water may result in increased risk of cancer (e.g., skin, bladder, lung, kidney, liver, prostate, and nasal passage) and is associated with noncancer effects, such as alterations in gastrointestinal, cardiovascular, hematological (e.g., anemia), pulmonary, neurological, immunological, and reproductive/developmental function. In response to this EPA rulemaking, FDA published the June 9, 2005 final rule. This final rule ensures that the minimum quality of bottled water, as affected by arsenic, 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 arsenic in bottled water?

The allowable level established by FDA for arsenic in bottled water is 10 micrograms (0.010 milligrams) per liter of water. (21 CFR 165.110(b)(4)(iii)(A)).

2. What analytical methods are used for determining compliance with the quality standard for arsenic in bottled water?

The analytical methods used for determining compliance with the quality standard for arsenic in bottled water are as follows:

- Method 200.8-- "Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Revision 5.4.
- Method 200.9-- "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption," Revision 2.2.

(21 CFR 165.110(b)(4)(iii)(E)(14)).