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Guidance for Industry

Bottled Water Quality Standard: Establishing an Allowable Level for di(2-ethylhexyl)phthalate

Small Entity Compliance Guide

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U.S. Department of Health and Human Services
Food and Drug Administration
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I. Introduction

On October 19, 2011, the Food and Drug Administration (FDA) published a final rule in the Federal Register (76 FR 64810) that amended its bottled water standard of quality regulations by establishing an allowable level for di(2-ethylhexylphthalate) (DEHP). The final rule is effective on April 16, 2012. As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for DEHP as often as necessary, but at least once each year under the current good manufacturing practice (CGMP) regulations for bottled water. Bottled water manufacturers also are required to monitor for DEHP at least once each year in their source water, unless the bottlers meet the criteria for source water testing exemptions under the CGMP regulations.

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 set forth in 21 CFR part 129 and part 165 concerning the contaminant DEHP. 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 Division of Plant and Dairy Food Safety, Office of Food Safety, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Background

In the Federal Register of August 4, 1993 (58 FR 41612), FDA published a proposal to revise the bottled water standard of quality regulations in 21 CFR part 103 (now 21 CFR 165.110(b)) to establish or modify the allowable levels in bottled water for 5 inorganic chemicals and 18 synthetic organic chemicals, and to maintain the existing allowable level for the inorganic chemical sulfate. As required under Section 410 of the Federal Food, Drug, and Cosmetic Act, FDA proposed these revisions in response to the publication by the Environmental Protection Agency (EPA) of a final rule (57 FR 31776; July 17, 1992) that established national primary drinking water regulations consisting of maximum contaminant levels (MCLs) for the same 23 chemicals and establishing an MCL for sulfate in public drinking water under the Safe Drinking Water Act. In a final rule published March 26, 1996 (61 FR 13258), FDA maintained its existing allowable level for sulfate and adopted the proposed allowable levels for the 5 inorganic chemicals and 17 of the synthetic organic chemicals. FDA deferred final action on the proposed allowable level of 0.006 milligrams/liter (mg/L) for the chemical DEHP in response to a comment.

In the Federal Register of April 1, 2010 (75 FR 16363), FDA reopened the comment period for the 1993 proposed rule to seek further comment on finalizing the allowable level for DEHP in the bottled water quality standard. In response to new information and comments received, FDA published the October 19, 2011 final rule. This final rule ensures that FDA's standards for the minimum quality of bottled water, as affected by DEHP, will be no less protective of the public health than those set by EPA for public drinking water.

III. Questions and Answers

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

   The allowable level established by FDA for DEHP in bottled water is 0.006 milligram per liter (mg/l) (21 CFR 165.110(b)(4)(iii)(C)).

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

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

   - Method 506, Rev. 1.1—"Determination of phthalate and adipate esters in drinking water by liquid/liquid extraction or liquid/solid extraction and gas chromatography with photoionization detection," U.S. EPA, 1995, EPA/600/R–95/131 (21 CFR 165.110(b)(4)(iii)(F)(21)), and

   - Method 525.2, Rev. 2.0—"Determination of organic compounds in drinking water by liquid-solid extraction and capillary column gas chromatography/mass spectrometry," U.S. EPA, 1995, EPA/600/R–95/131 (21 CFR 165.110(b)(4)(iii)(F)(22)).

3. Where can I find the analytical methods?

The analytical methods can be found in the following sources:

- EPA Method 506, Rev. 1.1, can be found in "Methods for the Determination of Organic Compounds in Drinking Water, Supplement III," EPA National Exposure Research Laboratory, EPA/600/R–95/131, August 1995, which can be accessed online at http://www.epa.gov/nscep/index.html.

- EPA Method 525.2, Rev. 2.0, can be found in "Methods for the Determination of Organic Compounds in Drinking Water, Supplement III," EPA National Exposure Research Laboratory, EPA/600/R–95/131, August 1995, which can be accessed online at http://www.epa.gov/nscep/index.html.