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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. FDA 1993-N-0259 (Formerly Docket No. 1993N-0085)]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its bottled water quality standard regulations by establishing an allowable level for the chemical di(2-ethylhexyl)phthalate (DEHP). As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for DEHP at least once each year under the current good manufacturing practice (CGMP) regulations for bottled water. Bottled water manufacturers are also required to monitor their source water for DEHP as often as necessary, but at least once every year unless they meet the criteria for source water monitoring exemptions under the CGMP regulations. This final rule will ensure 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 the Environmental Protection Agency (EPA) for public drinking water.

DATES: This rule is effective April 16, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of April 16, 2012.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1639. Hearing-impaired or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 4, 1993 (58 FR 41612), FDA published a proposal ("the 1993 proposed rule") to revise the bottled water quality standard 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 (FD&C Act), FDA proposed these revisions in response to the publication by EPA of a final rule (57 FR 31776; July 17, 1992) that established national primary drinking water regulations (NPDWRs) 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 (SDWA). 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 stating that the proposed allowable level conflicted with an existing prior sanction for this substance in § 181.27 ([21 CFR 181.27](#)).

In the **Federal Register** of April 1, 2010 ([75 FR 16363](#)), FDA announced that it was reopening 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. At the same time, FDA addressed the issue of the prior sanction for the use of DEHP under § 181.27, which resulted in deferral of final action in 1996. FDA also provided updates on the use of DEHP in bottled water bottles and lid gaskets, and on international standards for DEHP in bottled water. Finally, FDA provided information on analytical methods for measuring DEHP that were adopted by EPA after the 1993 proposed rule and sought comment on the possible inclusion of these methods in a final regulation.

II. Summary of and Response to Comments

The agency received 10 responses, each containing one or more comments, to the April 1, 2010, **Federal Register** document reopening the comment period for the 1993 proposed

rule. The agency previously received 13 responses, each containing one or more comments, to the 1993 proposed rule. Some comments addressed issues that are outside the scope of this final rule (*e.g.*, monitoring requirements, other chemicals, and food labeling), and thus will not be discussed here.

Most comments supported adoption of an allowable level for DEHP. As noted previously, one comment received in response to the 1993 proposed rule stated that the proposed allowable level for DEHP conflicted with an existing prior sanction for this substance in § 181.27. This comment also stated that DEHP is routinely used as a plasticizer in gaskets, and that such gaskets are permitted for use under relevant European national regulations. FDA responded to this comment in the April 1, 2010, **Federal Register** document. Briefly, FDA stated that the prior sanction for the use of DEHP in § 181.27 does not preclude the agency from establishing an allowable level for DEHP in the bottled water quality standard under § 165.110(b). FDA also stated that it appears that DEHP currently is not used in caps or closures for bottled water in the United States (Ref. 1), and that DEHP use is not permitted under European Commission regulations for plastic caps or plastic lid gaskets in metal caps (Ref. 2). Finally, FDA stated that several international organizations have adopted standards for DEHP that are the same or similar to the proposed allowable level of 0.006 mg/L, and that the International Bottled Water Association (IBWA), a trade association representing a large segment of the U.S. bottled water industry, adopted EPA's 0.006 mg/L standard for DEHP (40 CFR 141.61(c)) in its Model Code by 1995, suggesting that U.S. manufacturers already are able to meet the proposed level (Refs. 3 and 4). FDA did not receive any comments disagreeing with FDA's conclusions.

Two comments received in response to the April 1, 2010, **Federal Register** document opposed action related to DEHP in bottled water. The first comment stated that there was no reason to change current standards for plastic water bottles because evidence from two studies puts previous concerns to rest concerning the effects of DEHP consumption in humans. In response, FDA notes that it is establishing an allowable level for DEHP in bottled water, not changing standards for plastic bottles. Furthermore, FDA does not agree that the comment provided sufficient evidence to challenge EPA's finding that long-term, chronic exposure to DEHP above the MCL of 0.006 mg/L may have the potential to cause health effects in humans including damage to liver and testes, reproductive effects, and cancer (Ref. 5). Therefore, FDA continues to believe that it is appropriate to base its allowable level for DEHP in bottled water upon the MCL established by EPA for public drinking water.

A second comment received in response to the April 1, 2010, **Federal Register** document stated that DEHP does not leach into water in appreciable amounts and that prohibiting the use of DEHP would increase costs for consumers for beverages packaged in plastic bottles. However, this rule does not prohibit the use of DEHP; rather, it sets an allowable level for DEHP in bottled water. The allowable level for DEHP in bottled water is intended to address the potential presence of DEHP in water for any reason, not just leaching from bottles or caps. Furthermore, the comment did not provide any evidence to support or quantify its statement that DEHP does not leach into water in appreciable amounts. Finally,

FDA disagrees that the regulation would increase costs for consumers. Many U.S. manufacturers already appear to be meeting the allowable level for DEHP in bottled water (Refs. 3 and 4). In fact, information from industry suggests that DEHP currently is not used in bottled water caps or bottles in the United States (Refs. 1 and 6). Therefore, FDA does not agree with the comment's assertion that the rule prohibits the use of DEHP or its assertion that the rule would increase costs for consumers for beverages packaged in plastic bottles.

In the April 1, 2010, **Federal Register** document, FDA noted that EPA had updated its methods for DEHP analysis after FDA published the 1993 proposal. FDA made available the updated methods (Refs. 7 and 8) for comment on their possible inclusion in the final regulation. FDA did not receive any comments disagreeing with adoption of the updated methods.

III. Conclusion

The agency is adopting the allowable level for DEHP in the bottled water quality standard as proposed (58 FR 41612). Therefore, FDA is establishing in § 165.110(b)(4)(iii)(C) ([21 CFR 165.110\(b\)\(4\)\(iii\)\(C\)](#)), which includes allowable levels for pesticides and other synthetic organic chemicals, an allowable level for DEHP at 0.006 mg/L.

As a consequence, in accordance with FDA's current good manufacturing practice (CGMP) regulations for bottled water ([21 CFR part 129](#)), bottled water manufacturers will be required to monitor their source water and finished bottled water products for DEHP. Bottled water manufacturers will be required to monitor their source water for DEHP as often as necessary, but at a minimum frequency of once each year ([21 CFR 129.35\(a\)\(3\)](#)), unless they meet the criteria for source water monitoring exemptions under the CGMP regulations ([21 CFR 129.35\(a\)\(4\)](#)). Bottled water manufacturers will be required to monitor their finished products for DEHP at least once a year ([21 CFR 129.80\(g\)\(2\)](#)).

With respect to analytical methods for the determination of chemical contaminants, FDA is making the following changes in § 165.110(b)(4)(iii). In the revised § 165.110(b)(4)(iii)(F) introductory text and in new § 165.110(b)(4)(iii)(F)(21) and (b)(4)(iii)(F)(22), FDA is incorporating by reference EPA-approved analytical methods for determining compliance with the quality standard for DEHP in bottled water. FDA believes that these methods are sufficient to use for determining the level of DEHP in bottled water. These methods are contained in the manual entitled "Methods for the Determination of Organic Compounds in Drinking Water, Supplement III," EPA National Exposure Research Laboratory, EPA/600/R-95/131, August 1995.

Therefore, upon the effective date of this rule, any bottled water that contains DEHP at a level that exceeds the applicable allowable level will be deemed misbranded under section 403(h)(1) of the FD&C Act (21 U.S.C. 343(h)(1)) unless it bears a statement of substandard quality as provided by § 165.110(c)(3).

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Executive Order 12866: Cost Benefit Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 ([Pub. L. 104-4](#)). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The agency concludes that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs per entity of this rule are small, the agency also concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 ([Pub. L. 104-4](#)) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The Economic Impact Analysis of the 1996 final rule ([61 FR 13258](#)) revised the analysis set forth in the 1993 proposed rule ([58 FR 41612](#)) in response to comments received. Likewise, this final Economic Impact Analysis revises the analysis set forth in the 1993 proposed rule in response to comments received.

‡A. Need for Regulation

Section 410 of the FD&C Act (21 U.S.C. 349) ¹ requires that, whenever EPA prescribes interim or revised NPDWRs under section 1412 of the Public Health Service Act (The SDWA, 42 U.S.C. 300f through 300j-9), FDA consult with EPA and either amend its regulations for bottled drinking water in § 165.110 ([21 CFR 165.110](#)) or publish in the

Federal Register its reasons for not making such amendments. In accordance with section 410 of the FD&C Act, FDA published in the **Federal Register** of August 4, 1993 (58 FR 41612), a proposal to adopt EPA's MCL for DEHP as an allowable level in the bottled water quality standard. This action was in response to EPA's issuance of an NPDWR establishing an MCL for DEHP in public drinking water on July 17, 1992 (57 FR 31776). As described above, FDA deferred final action on the proposed allowable level for DEHP on March 26, 1996 (61 FR 13258). By finalizing the allowable level for DEHP in the bottled water quality standard, FDA is meeting the requirement in the FD&C Act to amend its regulations for bottled drinking water in response to EPA's establishment of an MCL for DEHP.

FOOTNOTE ¹ Section 410 of the FD&C Act was amended on August 6, 1996 to add subsection (b), related to contaminants for which EPA has promulgated NPDWRs under section 1412 of the SDWA. Specifically, this provision provides that, if FDA fails to issue a standard of quality regulation for a contaminant in bottled water not later than 180 days before the effective date of a NPDWR for that contaminant, EPA's NPDWR will apply to bottled water. FDA has interpreted this provision as not applying retroactively to EPA's NPDWR for DEHP.

Although DEHP is not expected to be found in bottled water in levels above the standard, FDA concludes that this rule is protective of public health because it will ensure that, should current conditions change, such as new sources of water or new manufacturing practices, the level of DEHP will remain low.

B. Costs

In the 1993 proposed rule, FDA stated that a single test can be used to analyze 23 contaminants, including DEHP, with costs of up to \$3,000 per sample. Comments submitted by IBWA in response to the 1993 proposed rule stated that a single test can be used for 14 contaminants, including DEHP and certain previously regulated contaminants, and that no additional testing costs would be required (Ref. 9). Although FDA is adopting new methods for DEHP analysis in this final rule (EPA Method 506, Rev. 1-1, and EPA Method 525.2, Rev. 2.0), EPA Method 525.2 tests for multiple currently regulated chemicals, including all the chemicals that were detected by the previously proposed method, EPA Method 525.1, Rev. 2.2. Since no additional testing is needed for DEHP, and since the costs of testing for DEHP have already been estimated in the 1993 proposed rule, FDA expects no additional testing costs resulting from the adoption of an allowable level for DEHP.

As discussed above, many U.S. manufacturers already appear to be meeting the allowable level (Refs. 3 and 4). Further, information from industry suggests that DEHP currently is not used in bottled water caps or bottles in the United States (Refs. 1 and 6). Thus, no reformulation costs are expected because DEHP is not expected to be found in bottled water in levels above the standard.

C. Benefits

In the Economic Impact Analysis of the 1993 proposed rule, FDA determined that, because none of the 23 contaminants including DEHP are expected to be found in bottled water above the levels of the standards, the benefits of the proposed rule were expected to be zero. Because the 23 contaminants, including DEHP, still are not expected to be found in bottled water at levels above the standards, benefits of this final rule continue to be zero. However, as stated in the Economic Impact Analysis in the 1996 final rule for the other contaminants (61 FR 13258), this rule continues to ensure that, should current conditions change, such as new sources of water or new manufacturing practices, the level of DEHP and other contaminants will remain low.

VI. Small Entity Analysis

FDA examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities.

FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the 1996 Economic Impact Analysis found that the final rule will not have a significant impact on a substantial number of small businesses.

As stated in the analysis of impacts, information from industry suggests that DEHP currently is not used in bottled water caps or bottles in the United States (Refs. 1 and 6). Furthermore, many U.S. manufacturers already appear to be meeting the allowable level (Refs. 3 and 4). Thus, no reformulation costs are expected because DEHP is not expected to be found in bottled water above the levels of the standard.

For the reasons stated above, we do not classify as costs of this final rule any voluntary expenses that some small firms may incur because they already chose to meet the new standards for DEHP set forth in this rule.

VII. Paperwork Reduction Act of 1995

FDA concludes that the provisions of this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3220).

VIII. Federalism

FDA has analyzed this rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption

provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 403A of the FD&C Act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: "* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce-(1) Any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g) * * *." FDA has interpreted this provision to apply to standards of quality (21 CFR 100.1(c)(4)).

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353, 2364 (1990)).

This final rule creates requirements that fall within the scope of section 403A(a) of the FD&C Act.

IX. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Memorandum of telephone conversation to John Rost, Crown Packaging Technology, from Lauren Robin, FDA, January 5, 2010.
2. European Commission, 2007, Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs, *Official Journal of the European Union*, 31.3.2007, L 91/17-36.
3. IBWA, 2007, IBWA Model Code, Version October 2007, accessed online at <http://www.bottledwater.org/public/pdf/2008-code-of-practice.pdf>.
4. E-mail from Bob Hirst, IBWA, to Lauren Robin, FDA, January 5, 2010.
5. U.S. EPA, Technical factsheet on di (2-ethylhexyl) phthalate (DEHP), accessed online at <http://www.epa.gov/safewater/pdfs/factsheets/soc/tech/dehp.pdf>.
6. Joseph K. Doss, IBWA, Testimony before the Subcommittee on Oversight and Investigations of the

Energy and Commerce Committee, United States House of Representatives, Hearing on Bottled Water Regulation, July 8, 2009, accessed online at <http://democrats.energycommerce.house.gov/Press-111/20090708/testimony-doss.pdf>.

7. U.S. EPA, EPA 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," 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, accessed online at <http://www.epa.gov/nscep/index.html>.

8. U.S. EPA, EPA Method 525.2, Rev. 2.0-"Determination of organic compounds in drinking water by liquid-solid extraction and capillary column gas chromatography/mass spectrometry," 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, accessed online at <http://www.epa.gov/nscep/index.html>.

9. International Bottled Water Association, comment to FDA Docket Number 1993N-0085, October 4, 1993.

List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 165 is amended as follows:

PART 165-BEVERAGES

- 1. The authority citation for 21 CFR part 165 continues to read as follows:

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

- 2. In § 165.110, in the table in paragraph (b)(4)(iii)(C), alphabetically add an entry for "Di(2-ethylhexyl)phthalate (117-81-7)"; revise paragraph (b)(4)(iii)(F) introductory text; and add new paragraphs (b)(4)(iii)(F)(21) and (b)(4)(iii)(F)(22) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(4) * * *

(iii) * * *

(C) The allowable levels for pesticides and other synthetic organic chemicals (SOCs) are as

follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
* * * * *	
Di(2-ethylhexyl)phthalate (117-81-7)	0.006
* * * * *	

* * * * *

(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(1) through (b)(4)(iii)(F)(22) of this section and described, unless otherwise noted, in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, EMSL, EPA/600/4-88/039, December 1988, or in "Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1," Office of Research and Development, EMSL, EPA/600/4-90/020, July 1990, or in "Methods for the Determination of Organic Compounds in Drinking Water, Supplement III," EPA National Exposure Research Laboratory, Office of Research and Development, EPA/600/R-95/131, August 1995, including Errata, November 27, 1995. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and [1 CFR part 51](#). Copies of these publications are available from National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. You may inspect a copy at the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860 or at the National Archives and Records Administration (NARA). Hearing-impaired or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339. For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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(21) 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," EPA/600/R-95/131, 1995, (applicable to di(2-ethylhexyl) phthalate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and [1 CFR part 51](#), or

(22) Method 525.2, Rev. 2.0-"Determination of organic compounds in drinking water by liquid-solid extraction and capillary column gas chromatography/mass spectrometry," EPA/600/R-95/131, 1995, (applicable to di(2-ethylhexyl)phthalate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and [1 CFR part 51](#).

* * * * *

Dated: October 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-26707 Filed 10-18-11; 8:45 am]

BILLING CODE 4160-01-P

[REFERENCES] 21 CFR 103 , 21 CFR 181 , 40 CFR 141 , 21 CFR 129 , 21 CFR 100 , 1 CFR 51

[CITATIONS] 21 CFR 165

[CITREFS] 21CFR:FOODDG

[AGENCYREFS] AADPAADY

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