

FDA Announces Allowable Level for DEHP in Bottled Water

October 19, 2011

On October 19, 2011, the Food and Drug Administration (“FDA”) published a [final rule](#) amending its bottled water quality standard regulations by establishing an allowable level of di (2-ethylhexyl)phthalate (“DEHP”). The new DEHP limit and related requirements will take effect on April 16, 2012. Under Section 410 of the Food, Drug, and Cosmetic Act (“FDCA”), the FDA is required to promulgate bottled water regulations whenever the Environmental Protection Agency (“EPA”) creates or revises its standards for drinking water. The FDA’s final rule, which will be codified at 21 C.F.R. 165.110(b)(4)(iii)(C), is designed to ensure that bottled water meets the same DEHP limits as those set by the EPA for drinking water. The FDA’s final rule also is consistent with the standards set by the [International Bottled Water Association](#) for its members. Specifically, the FDA’s new rule includes the following:

- Bottled water may not contain more than 0.006 milligrams/liter (mg/L) of DEHP or the product will be deemed misbranded under Section 403(h)(1) of the FDCA;
- In accordance with FDA current good manufacturing practice (“CGMP”), bottled water manufacturers will be required to monitor their source water for DEHP as often as necessary, but at least once a year, unless they meet the criteria for exemptions under 21 C.F.R. § 129.35.
- Manufacturers will also be required to monitor finished products for DEHP at least once a year; and
- The FDA will determine compliance with the new rule by using the EPA’s analytical methods for measuring DEHP in bottled water.