

● ●


A M E R I C A N B E V E R A G E
A S S O C I A T I O N

January 31, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rm. 1061 (HFA-305)
Rockville, MD 20852

Re: Comments to the Proposed Rule for Arsenic Levels in Bottled Water
(Docket No. 2004N-0416)

Dear Sir or Madam:

The American Beverage Association ("the Beverage Association") is pleased to submit these comments to the Food and Drug Administration ("FDA" or the "Agency") on its proposed rule for arsenic levels in bottled water.¹

Formerly known as the National Soft Drink Association ("NSDA"), the Beverage Association is the national trade organization of the beverage industry.² While the Association's member companies produce 95% of all soft drinks consumed annually in the United States, they also produce and distribute purified water, ready-to-drink teas, sports drinks, juice and juice-

¹ 69 Fed. Reg. 70082 (Dec. 2, 2004).

² On November 11, 2004, NSDA announced that it had changed its name to the American Beverage Association to better reflect the expanded range of non-alcoholic beverages the industry produces.

2004N-0416

C1

based beverages, and all other carbonated and non-carbonated products. In addition, the vast majority of the beverage licensors who manufacture concentrates and/or syrups from which soft drinks and other beverages are made belong to the Association. It is on behalf of these members that the Beverage Association submits these comments.

In short, the Beverage Association supports FDA's proposed rule to establish the Environmental Protection Agency's ("EPA's") maximum contaminant level ("MCL") for arsenic (i.e., 10 parts per billion ("ppb")) as a standard of quality for bottled water.³ Importantly, the Association agrees with FDA's conclusion that § 403A(a)(1) of the Federal Food, Drug and Cosmetic Act ("FD&C Act" or the "Act") (21 U.S.C. § 343A(a)(1)) expressly preempts any state law that is inconsistent with federal food standards of identity, including the standard of quality for bottled water. Further, FDA has fulfilled its obligation under Executive Order 13132 and has properly concluded that the preemptive effects of the proposed rule, when finalized, are consistent with the principles of federalism. Therefore, the American Beverage Association respectfully requests the Agency to finalize the arsenic levels for bottled water as proposed.

I. FDA Standards of Identity Preempt State Laws and Requirements

The Nutrition Labeling and Education Act of 1990 ("NLEA") provided for national uniformity of most food labeling requirements by preempting state and local requirements that are not identical to federal requirements.⁴ Specifically, for food standards of identity, the FD&C Act provides that a state may not "establish or continue in effect...a standard of identity for a food that is not identical to [the federal standard]."⁵ With this provision, Congress clearly expressed its intent to preempt any state law that is inconsistent with the federal requirements for a food standard of identity.

³ 66 Fed. Reg. 6976 (Jan. 22, 2001).

⁴ Pub. L. No. 101-535, § 6(a), 104 Stat. 2353, 2362-63 (Nov. 8, 1990), codified at 21 U.S.C. §343-1.

⁵ FD&C Act § 403A(a)(1). (21 U.S.C. § 343-1(a)(1)).

Indeed, FDA has reiterated this conclusion in numerous rulemakings and relied on this statutory authority in promulgating the bottled water regulations. FDA issued the bottled water standard of identity, which incorporated the previously existing standard of quality, to ensure "a uniform federal definition [so] that consumers will be able to purchase bottled water products that are informatively and consistently labeled throughout the country."⁶ Moreover, FDA stated that "under [NLEA], such a standard will preempt any state standards that are not identical to it."⁷

Therefore, based on the clear intent of Congress, contaminant levels that are established as part of the bottled water standard of identity, such as the proposed arsenic level, will preempt existing state laws to the extent that they are inconsistent with the federal standard.

II. FDA has Properly Concluded that the Preemptive Effects of the Proposed Rule Conforms with Executive Order 13132

Under Executive Order 13132, federal agencies must adhere to specific criteria when formulating and implementing policies that have federalism implications. Federal agencies must examine the constitutional and statutory authority supporting the action and carefully assess the necessity for such action. In addition, when taking action that preempts state law, agencies must: (1) act in strict accordance with the governing law; (2) consult with state and local officials; and (3) provide states with notice and an opportunity to participate in the rulemaking proceedings.⁸

For contaminants that EPA has established a maximum contaminant level ("MCL") under the Safe Drinking Water Act, FDA is required to: (1) issue a standard of quality regulation for that contaminant in bottled water; or (2) make a finding that such a regulation is not necessary to protect the public health.⁹ FDA has determined arsenic MCL set forth by EPA is

⁶ 58 Fed. Reg. 393 at 395 (Jan. 5, 1993).

⁷ Id.

⁸ Executive Order 13132, 64 Fed. Reg. 43255 (Aug. 10, 1999). See also, Memorandum for Heads of Executive Departments and Agencies, and Independent Regulatory Agencies from John T. Spotila, Administrator of Information and Regulatory Affairs, Office of Management and Budget, Re: Guidance for Implementing E.O. 13132 (Oct. 28, 1999).

⁹ FD&C Act § 410(b). (21 U.S.C. § 349(b)).

appropriate for bottled water and has incorporated by reference EPA's approved analytical methods for determining compliance. FDA has limited its regulatory action by maintaining a single MCL and method of analysis for both drinking and bottled water.

Also, state and local officials have been adequately consulted on the proposed arsenic levels through EPA's rulemaking proceedings. As provided in its final rule, EPA stated that it "consulted with state and local officials early in the process of developing the [arsenic level] to permit them to have meaningful and timely input into its development."¹⁰ EPA conducted four stakeholder meetings in addition to public meetings. During these meetings and throughout the rulemaking process, state and local officials have communicated with EPA regarding the arsenic level, which assures FDA of sufficient input by these authorities.

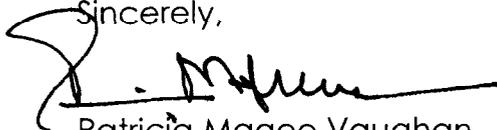
Finally, as stated by FDA in its federalism analysis, EPA's issuance of an MCL for arsenic in public drinking water provided notice of possible FDA action for the bottled water standard. Additionally, the proposed rule provides ample notice and opportunity to participate in FDA's rulemaking proceedings. Therefore, FDA has properly complied with the requirements of Executive Order 13132 and determined that the proposed rule comports with the principles of federalism.

¹⁰ 66 Fed. Reg. 6976 at 7052 (Jan. 22, 2001).

III. Conclusion

The FD&C Act clearly establishes federal preemption in instances where state laws are inconsistent with federal food standards of identity established by the FDA. The federalism analysis conducted by FDA accurately determines that the proposed rule, when finalized is consistent with Executive Order 13132. Therefore, the American Beverage Association respectfully requests the Agency to finalize the proposed arsenic level.

Sincerely,



Patricia Magee Vaughan
Vice President, Regulatory Affairs
General Counsel
American Beverage Association