



American Water Works Association
Government Affairs Office

Dedicated to Safe Drinking Water

1401 New York Avenue, NW
Suite 640, Washington, DC 20005
<http://www.awwa.org>

(202) 628-8303 Fax (202) 628-2846

April 20, 2000

5052 00 APR 20 AM 12:16

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. 97N-0436/FDA Draft Study Report: Feasibility of Appropriate
Methods of Informing Customers of the Contents of Bottled Water**

Gentlemen:

Enclosed are the American Water Work's Association's comments on the Food and Drug Administration's draft study report on the feasibility of appropriate methods of informing customers of contents of bottled water.

Yours Sincerely,

J. Alan Roberson, P.E.
Director of Regulatory Affairs

Enclosures

- cc: Cynthia Dougherty—USEPA OGWDW
- Rob Allison—USEPA OGWDW
- Rob Renner
- Tom Curtis
- Ed Baruth
- Steve Via
- Jeanne Bailey
- Clare Haas
- Doug Marsano

F:\home\jar\letters\fdabottledwaterccrcommentscover

97N-0436

Headquarters Office:
6666 W. Quincy Avenue, Denver, CO 80235
(303) 794-7711 Fax (303) 795-1440

C 38

**Final Comments by the American Water Works Association
On the Food and Drug Administration Draft Study Report:
Feasibility of Appropriate Methods on Informing
Customers on the Contents of Bottled Water
(65 FR 8718)**

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 56,000 plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,200 utilities that supply roughly 80 percent of the nation's drinking water.

The comments provided herein reflect the consensus of the AWWA that, given the depth and breadth of its representation, also reflect the predominant view of the nation's drinking water professionals. It is therefore appropriate that these AWWA comments be heard on behalf of the drinking water community in general.

The Public's Right to Know. AWWA strongly supports the public's right to know the quality of their drinking water. We actively supported the consumer confidence report (CCR) provisions (with the inclusion of bottled water) in the 1996 Safe Drinking Water Act (SDWA) Amendments. Subsequent to the 1996 SDWA Amendments, we worked closely with the Environmental Protection Agency (EPA) to ensure that the CCR provisions were clear, concise, sensible, and implementable. AWWA developed an online template (CCRBuilder) and conducted extensive training to assist utilities in developing quality CCRs.

Unfortunately, there is a significant portion of drinking water, i.e, bottled water, that is not yet subject to similar federal requirements on the public's right to know. Consumers are increasingly purchasing bottled water as an alternative to soft drinks, juices, and other beverages. The bottled water industry has increased dramatically over the past decade to \$5 billion share of the beverage market. Because bottled water has become such a popular beverage, the public should be informed about its source and quality.

Bottled water is also sometimes used as a replacement for tap water in emergency situations. After a natural disaster, delivery of bottled water is sometimes the only option to maintain basic sanitation. However, it should be noted that in times of emergency, breweries sometimes shift their production lines to produce bottled water. Under such emergency conditions, these breweries shouldn't be required to comply with the future bottled water CCR requirements. Regulatory requirements that get in the way of good sanitation practices under emergency conditions should be avoided.

Perhaps most importantly, bottled water is often considered as an alternative for the immunocompromised and other sensitive subpopulations. It is critical that these consumers, and their health care providers, have consistent, accurate, up to date, and easily accessible information on the contents of bottled water so that they can easily make informed decisions on their choice of drinking water. For example, the Centers for Disease Control and Prevention (CDC) and EPA, in their *Guidance for People with Severely Weakened Immune Systems*, recognized that "...Any bottled water treated by distillation or reverse osmosis before bottling assures *Cryptosporidium* removal". Clearly, this class of consumers needs to be able to easily distinguish between brands of bottled water that provide this level of treatment and brands that don't.

Clearly, consumers are making choices about bottled water based on individual health decision criteria. Some consumers choose bottled water as a alternative to centrally treated tap water, even in non-emergency situations. For these reasons, bottled water suppliers should be subject to the same federal right to know requirements as water utilities.

Regulatory Schedule. AWWA is concerned with the delay that the Food and Drug Administration (FDA) has experienced in releasing this draft feasibility study. The 1996 Safe Drinking Water Act (SDWA) Amendments required that this draft study be completed in 18 months, or by February 6, 1997. The 1996 SDWA Amendments also required that the final study be completed in 30 months, or by February 6, 1998. So the FDA is substantially behind schedule for both the draft and final reports, and the schedule for any future regulation resulting from these reports is not clear.

We are concerned with the future schedule for the regulation that would result from this final report, the implementation of this final regulation, and the timeframe for the bottlers to ultimately comply with the regulatory requirements. The intent of the 1996 SDWA Amendments was to have public information for the contents of bottled water available in the same general timeframe as the drinking water utility Consumer Confidence Reports (CCRs). Water utilities published their first CCRs in 1999, and are in the process developing their second CCRs for publication by July, 2000. It is not clear from this *Federal Register* notice when the bottlers would be required to have some minimum information on the label, and have more detailed information easily accessible.

Label Requirements. AWWA recommends that FDA develop a regulation under the Federal Food, Drug, and Cosmetic Act (FFDCA) for minimum label requirements for bottled water contents. The minimum label requirements should contain the source of water (such as well, spring, public water supply, etc.) and how the water was further treated by the bottler. Example language based on these minimum requirements follows:

"This water came from (name of source) and was further treated by (treatment name(s)). For more information on contents, please call 800-XXX-XXXX (or go to www.xxxxxxxxxxx.com. [optional])"

For most bottled waters, this requirement would add 25-30 words to the label. The labels for many bottled water already carries most of this information. The key is to make this a federal requirement so that the label information is consistent, accurate, up to date, and easily accessible. Voluntary trade association standards, while admirable, don't provide 100% consistent label information across all brands of bottled water. Again, the federal standards should provide for consistency for both public water supplies and bottled water.

AWWA recommends that a toll-free number be a label requirement. A toll-free number is essential to provide the consumers an easy opportunity to obtain more detailed information. Paying for a long-distance call would be a disincentive for consumers to obtain the more detailed information. Providing a mailing address would add more wording to the label, and again, serves as a disincentive to obtaining the more detailed information. The cost for a toll-free number, with an answering machine to leave the name and address for mailing the detailed information, is minimal.

If the bottler has a Website that is used for marketing or other purposes, then the URL for the Website should be provided on the label. If a bottler later starts a Website, then the URL should be added to the label within a reasonable length of time to allow the depletion of the existing inventory with the old label. This label requirement would only be applicable to bottlers with existing Websites.

This concept of providing a toll-free number (with the URL being optional) for consumers to obtain more information fits in with FDA's combination report as detailed in the *Federal Register*. We strongly recommend that FDA develop a federal regulation under the FFDCA that requires, at a minimum, the label information suggested above.

Bottled Water CCR. To avoid confusion, the requirements for a bottled water CCR should be as consistent as possible with the water utility CCR requirements. Bottled water CCRs should be updated on an annual basis, and record retention requirements should mirror the water utility requirements. Reports should include information on the source of water (including a map), type of treatment(s), levels of contaminants detected, FDA allowable levels, plain English descriptions on the health concerns for detected contaminants, and the phone numbers for EPA and FDA hotlines for more information. These CCRs should be available on request by consumers using the toll-free number, and posted on the bottlers' Websites, where applicable.

AWWA recommends that bulk water suppliers (jugs used in offices, etc.) be required to annually deliver a bottled water CCR to their customers. An exchange of paperwork already exists for bulk water deliveries with the signing for the delivery and/or mailing of the invoice, and the bottled water CCR should be included on an annual basis with one of these paperwork exchanges.

Bottled Water Standards. Beyond the bottled water CCR requirements, there is a need to better educate consumers on the differences between the drinking water standards set by the Environmental Protection Agency (EPA) and the bottled water standards set by the Food and Drug Administration (FDA). While the FDA regulations generally mirror the EPA regulations, there are major differences in monitoring, compliance determinations, etc. These differences are not very clear to the consumer at this time. The CCR requirements are a starting point, but more work is needed.

Conclusion. Clearly, the intent of Congress in the 1996 SDWA Amendments was to have all drinking water meet the same quality and right to know requirements. Water utilities and bottlers should have a "level playing field" when it comes to federal quality and right to know requirements. Obviously, a full and complete bottled water CCR cannot fit on a typical bottled water label. But the minimum label information suggested above would provide the consumer some basic information to make an informed decision. Easily accessible, detailed CCR information would then provide an avenue for those consumers that want the more detailed information to obtain it.

F:\home\jar\comments\bottledwaterccrstudy



American Water Works Association

Government Affairs Office / 1401 New York Avenue, N.W. / Suite 640 / Washington, D.C. 20005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
(301) 827-6880