

# **RECENT DEVELOPMENTS IN BOTTLED WATER QUALITY AND SAFETY**

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## **I. INTRODUCTION**

Bottled water is regulated through a comprehensive regulatory system at the federal and state level. Over the past several years, the US Food and Drug Administration (FDA) adopted several new bottled water quality standards, as well as issued guidance and regulations to address increased security threats. These programs, in combination with guidelines developed and followed by the bottled water industry, serve to further enhance the safety of bottled water.

The Drinking Water Research Foundation<sup>1</sup> (DWRf) is an independent not-for-profit 501(C)(3) organization that was founded in 1984 to sponsor peer-reviewed scientific research that addresses the production of safe and affordable drinking water, including bottled water. DWRf has prepared this report to summarize recent developments in the protection and regulation of bottled water.

## **II. GENERAL OVERVIEW: REGULATORY STATUS OF BOTTLED WATER IN THE US**

Bottled water is among the foods most highly regulated by FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §321 et seq.). Under FDA jurisdiction, bottled water is subject to extensive general food safety and labeling requirements, including prohibitions on misbranding and adulteration (21 C.F.R. §§101 and 109). Also, FDA has extensive enforcement capabilities, including the power to inspect food manufacturing facilities, issue warning letters, request voluntary recalls, and issue seizure or injunction against products or companies out of compliance, including seeking criminal prosecutions. Collectively, these requirements are the cornerstone of the very safe food supply enjoyed in the United States.

In addition to these general food provisions, bottled water is also required to meet federal standards applicable specifically to bottled water, including Good Manufacturing Practices (GMPs) (21 C.F.R. §§110 and 129) and specific identity and quality requirements (21 C.F.R. §165.110). The GMPs for bottled water apply to every aspect of production, from source water protection, through processing, to finished water sampling.

The FFDCA also directs FDA to consider adopting bottled water standards similar to those adopted by the Environmental Protection Agency (EPA) for “tap water.” Section 410(b) of the FFDCA requires that within 180 days of the effective date of any new EPA National Primary Drinking Water Regulation, FDA shall promulgate a Standard of Quality (SOQ) for bottled water or make a finding that such a regulation is not necessary. To ensure FDA reviews the relevant EPA regulations, the FFDCA includes a “hammer provision,” which stipulates that if FDA does not promulgate a standard or publish in the Federal Register a reason for not doing so within the 180-day timeframe, then the EPA standard automatically becomes applicable to bottled water. Therefore, by law, bottled

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<sup>1</sup> <http://www.dwrf.info>.

water standards must be at least as stringent and protective of public health as EPA tap water standards. States can also regulate bottled water as well as perform functions that can include laboratory certification and source water approval.

The safety of bottled water is further enhanced through an industry program developed by the International Bottled Water Association<sup>2</sup> (IBWA), which has developed the IBWA Model Code<sup>3</sup> designed to promote the safety and high quality of bottled water. The IBWA Model Code consists of a robust system to ensure that members meet strict standards for source water protection, production hygiene and security, Good Manufacturing Practices, finished product monitoring and product labeling. Additionally, the IBWA Model Code is intended for use as a model "regulation" or "legislation" in states or municipalities.

To ensure adherence with federal and state regulatory standards and these industry guidelines, a program of annual facility inspections has been established. IBWA members, as a requirement of membership, must submit to an annual unannounced plant inspection administered by the independent NSF International<sup>4</sup> (NSF). NSF is considered one of the world leaders in standards development, product certification, education, and risk-management for food, water and indoor air. NSF inspections of IBWA member facilities consist of examination of the quality and testing records, reviews of all areas of plant operation, confirmation that the facility is in compliance with FDA Standards of Quality, Good Manufacturing Practices, and applicable state regulations as well as the IBWA Model Code.

### **III. RECENT REGULATORY DEVELOPMENTS**

The following sections summarize recent FDA standards activities related to bottled water.

#### **A. Uranium**

In March 2003 (21 C.F.R. §165.110(b)(5)(i)(D); 68 Fed. Reg. 9873), FDA published a bottled water quality standard for uranium of 30 pCi/L, which is the same standard in the final rule adopted by EPA in December 2000 (40 C.F.R. §141.66(e); 65 Fed. Reg. 76707). The FDA rule also adopted monitoring requirements for source and product water. FDA's direct final rule became effective in December 2003.

#### **B. Disinfection Byproducts**

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<sup>2</sup> The International Bottled Water Association (IBWA) is the authoritative source of information about all types of bottled waters. Founded in 1958, IBWA's membership includes US and international bottlers, distributors and suppliers. Consumers can contact IBWA at 1-800-WATER-11 or log onto IBWA's web site ([www.bottledwater.org](http://www.bottledwater.org)) for more information about bottled water and a list of members' brands.

<sup>3</sup> [http://www.bottledwater.org/public/pdf/IBWA\\_Model\\_Code\\_2003\\_rev\\_Jun03.pdf](http://www.bottledwater.org/public/pdf/IBWA_Model_Code_2003_rev_Jun03.pdf).

<sup>4</sup> <http://www.nsf.org>.

FDA published a direct final rule in March 2001 (21 C.F.R. §165.110; 66 Fed. Reg. 16858) that established allowable levels for disinfection byproducts (DBPs) that may result from the use of disinfectants to treat bottled water. The FDA rule was issued in response to EPA’s Stage 1 Disinfection Byproducts Rule (promulgated on December 16, 1998; 63 Fed. Reg. 69390), which addresses potential public health effects from the presence of disinfectants and DBP’s in drinking water. FDA adopted the same standards that EPA adopted in its regulation, as follows:

Contaminant	EPA Primary Drinking Water Regulation (mg/l)	FDA Water Quality Levels (mg/l)
Bromate	0.01	0.01
Chlorite	1	1
Haloacetic Acids	0.06	0.06
Total Trihalomethanes	0.08	0.08
Chloramine	4	4
Chlorine	4	4
Chlorine Dioxide	0.8	0.8

Bottled water companies that do not use a public water system as the source of their water, and whose source water has not been treated with a chlorine-based disinfectant or ozone, do not have to test their source water for the residual disinfectants and DBP’s (21 C.F.R. §129.35(a)(4)(iii)).

#### C. Arsenic

EPA established an arsenic drinking water standard of 10 ppb for public drinking water on January 22, 2001 (40 C.F.R. §141.62(b)(16); 66 Fed. Reg. 6976). The regulation provides public water systems until January 23, 2006 to comply with this standard.

IBWA wrote to the Office of Management and Budget (OMB) in May 2002 encouraging FDA to adopt a 10 ppb standard for bottled water. In response, FDA indicated plans to release a proposed arsenic standard for bottled water by September 2004. Additionally, while public water systems are not yet required to comply with the 10 ppb standard, the bottled water industry has already adopted the more stringent 10 ppb limit for arsenic as part of the IBWA Model Code.

#### D. Surface Water Treatment Rule

On December 16, 1998, EPA published the final Interim Enhanced Surface Water Treatment Rule (IESWTR) to control risks associated with *cryptosporidium*<sup>5</sup> contamination of surface water or groundwater sources under the influence of surface water (63 Fed. Reg. 69477). On July 5, 2001, FDA announced that it had reviewed the

<sup>5</sup> The ingestion of cryptosporidium oocysts can cause gastrointestinal illness. While cryptosporidiosis generally is considered a self-limiting disease, it can be chronic and life threatening in immunocompromised individuals.

IESWTR and concluded that there was no need to issue a standard of quality regulation for bottled water to address *Cryptosporidium* (66 Fed. Reg. 35439). FDA concluded that such a regulation was not necessary to protect public health because bottled water is unlikely to be contaminated with *Cryptosporidium* since, most bottled water is not produced from surface water or ground water under the influence of surface water and where the bottled water source is from a regulated public water system, the source water is already controlled through the EPA program. IBWA's Model Code stipulates:

*Bottled water which originates from a source which is not protected from surface contamination shall be subjected to ozonation, filtration rated at one micron, or another effective process which removes or inactivates the cysts of the parasites Giardia and Cryptosporidium.*

Note that on August 11, 2003, EPA published the Long Term 2 Enhanced Surface Water Proposed Rule<sup>6</sup> (68 Fed. Reg. 47639) to extend the IESTWR regulation from large water supply systems to all size community and non-community water supply systems. Since this rule merely extends the coverage of the surface water regulation, it is not expected to impact bottled water.

#### E. Heterotrophic Plate Count

Under EPA's tap water program, a low Heterotrophic Plate Count (HPC) bacteria measurement (<500 CFU/ml) is considered to demonstrate that an adequate disinfectant residual is present (40 C.F.R. §141.72). Bottled water critics often cite the lack of an HPC standard for bottled water, as an indication that bottled water is not adequately protected from microbiologic contamination. However as discussed below, scientists worldwide do not believe that HPC is an appropriate indicator of pathogenic biologic contamination.

The World Health Organization (WHO) recently reviewed the public health significance of HPC. In April 2002, a committee of microbiology and public health experts was convened by WHO in Geneva, Switzerland, to consider the public health significance of HPC in drinking water. The meeting was attended by 31 participants from Australia, Canada, France, Germany, Italy, Japan, the Netherlands, South Africa, Switzerland, UK and USA.<sup>7</sup>

As noted in the WHO Report,<sup>8</sup> exposure to HPC is far greater through foodstuffs than through drinking water. More importantly, the Expert Committee concluded that HPC itself does not present a risk to human health. As indicated in section 2.2 of the Report:

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<sup>6</sup> <http://www.epa.gov/fedrgstr/EPA-WATER/2003/August/Day-11/w18295a.htm>.

<sup>7</sup> The DWRf sponsored technical research presentations at the WHO Expert Meeting by DWRf Trustee Stephen C. Edberg, Ph.D., ABMM, Yale University School of Medicine, and the DWRf Research Director at the time, Cindy Yablonski. These technical papers are to be published in the International Journal of Food Protection.

<sup>8</sup> World Health Organization, "Heterotrophic Plate Count Measurement in Drinking Water Safety Management" (WHO/SDE/WSH/02.10).

*[t]here is no evidence that HPC values alone directly relate to health risk either from epidemiological studies or from correlation with occurrence of waterborne pathogens. They are therefore unsuitable for public health target setting or as sole justification for issuing 'boil water' advisories.*

Rather than focus on the presence of HPC in bottled water, the WHO experts advocated that systems adopt a comprehensive Water Safety Plan approach, including provisions for monitoring the various steps in the supply chain, management plans describing action to be undertaken under normal conditions and extreme events, and systematic independent surveillance.

It is significant to note that IBWA's Model Code already embodies requirements comparable to those advocated by the WHO Expert Committee.

The WHO Expert Committee's view of the lack of health concern associated with HPC in water was previously expressed by FDA. In a 1993 rulemaking, FDA noted that there was no need to regulate HPC in bottled water, as these bacteria are part of the natural flora, they do not colonize the digestive tract of humans and as such do not pose a health risk.

#### **IV. SECURITY ISSUES**

Reflecting the increased security threats of the last few years, FDA and the bottled water industry have embarked on an extensive program to help ensure the security of bottled water. The industry has incorporated into the IBWA Model Code provisions governing Product Quality and Security. Those provisions enhance the guidance FDA issued in March 2003<sup>9</sup> on measures that food establishments should take to minimize the risk of tampering or other malicious, criminal or terrorist actions. The FDA guidance recommends that food establishment operators adopt programs that ensure adequate staff screening and supervision, as well as limiting access to sensitive areas. FDA recommends that operators closely regulate suppliers, contractors, transporters, and have a clear system for inspecting and labeling both incoming materials and outgoing products.

Additionally, under the Public Health Security and Bioterrorism Preparedness Response Act of 2002 (Pub. L. No. 107-188), FDA developed security regulations that apply to facilities processing and packaging food, food additives and food contact materials. In late 2003, several interim final and proposed rules applicable to bottled water were issued including:

- Registration of Food Facilities (21 C.F.R. §§1 and 20; 68 Fed. Reg. 58894) – Interim final rule requires owners, operators, or agents of a foreign or domestic facility where food is manufactured/processed, packed, or held, to

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<sup>9</sup> See Guidance for Industry Food Producers, Processors and Transporters: Food Security Preventive Measures Guidance, <http://www.cfsan.fda.gov/~dms/secguid6.html>.

submit a registration to the FDA that includes basic information about the facility, emergency contact information, and the categories of food the facility handles.

- Prior Notice of Imported Food (21 C.F.R. §1; 68 Fed. Reg. 58974) – Interim final rule requires FDA to receive prior notice before imported food reaches the US port.
- Establishment and Maintenance of Records (21 C.F.R. §§1 and 11; 68 Fed. Reg. 25187) – Proposal requires manufacturers, processors, packers, transporters, distributors, receivers, holders, and importers of food to keep records identifying the immediate previous source from which they receive food, as well as the immediate subsequent recipient, to whom they sent food.
- Administrative Detention of Food for Human or Animal Consumption (21 C.F.R. §§1 and 16; 68 Fed. Reg. 25241) – Proposal implements FDA's new authority to detain any article of food for which there is credible evidence or information that the article poses a threat of serious adverse health consequences or death to human or animals.

Additional background on FDA's security regulations can be found at <http://www.foodsafety.gov/~fsg/bioterr.html>.

The IBWA Model Code expands on these security provisions by requiring bottled water facilities to prepare and adopt a Hazard Analysis and Critical Control Point (HACCP) program. The HACCP system, which is intended to minimize the potential for contamination incidents, has been advocated by FDA for select food groups including seafood and juice. Also, the United States Department of Agriculture (USDA) requires the use of HACCP in meat and poultry manufacturing facilities. The system was first developed over 30 years ago to ensure the US Space Program's food safety is based on a documented process of hazard identification, mitigation and record keeping.

HACCP<sup>10</sup> addresses food safety according to seven principles including:

- Analyze hazards;
- Identify critical control points;
- Establish preventive measures with critical limits for each control point;
- Establish procedures to monitor the critical control points;
- Establish corrective actions to be taken when monitoring shows that a critical limit has not been met;
- Establish procedures to verify that the system is working properly; and,
- Establish effective record-keeping documenting the HACCP system.

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<sup>10</sup> <http://www.cfsan.fda.gov/~lrd/bghaccp.html>.

The IBWA Model Code specifically requires members to develop HACCP plans, stating:

*Each IBWA member bottled water plant shall develop and maintain a Hazard Analysis and Critical Control Point (HACCP) program. As a part of the program, the plant shall develop and write a HACCP Plan that addresses product safety with respect to the seven principles of HACCP, as defined by the Codex Alimentarius Commission and the U.S. Food and Drug Administration.*

The IBWA Model Code provides additional details on the issues that should be considered in developing a HACCP Plan. As such, IBWA members that adhere to the IBWA Model Code provide an added level of product security over and above FDA's mandatory requirements.

## **V. CONSUMER INFORMATION - ACCESS TO WATER QUALITY INFORMATION**

Section 114(b) of the 1996 Safe Drinking Water Act Amendments mandated that FDA publish a study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water. In August 2000, FDA published in the Federal Register (65 Fed. Reg. 51833) its report entitled "Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water." This study examined potential methods for conveying water quality information to consumers. FDA focused its analysis on the type of information that would be analogous to that required by public water systems pursuant to the consumer confidence report<sup>11</sup> (CCR). The CCR is largely directed at providing consumers with a description of the level of contaminants in the drinking water.

In assessing the relevance of the CCR requirements to bottled water, FDA determined that, except for required information unique to public drinking water systems (*e.g.*, definition and statement about tap water Maximum Contaminant Level Goals), it was feasible for bottled water producers to provide CCR-type information.<sup>12</sup> However, with regards to dissemination of this information, FDA determined that for various reasons it would not be feasible to include on a bottled water label all of the information contained in a CCR.

FDA was particularly concerned that the bottle water label generally provides too small a space to contain all of the CCR analogous information, and that the cost and feasibility of keeping the label current due to changing test results, could impede the accuracy of the reported information. Similarly, FDA determined that distributing information at retail

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<sup>11</sup> On August 19, 1998 (63 Fed. Reg. 44511), EPA issued a final rule requiring public water systems to provide an annual consumer confidence report describing the level of contaminants in the drinking water purveyed by that system.

<sup>12</sup> FDA acknowledged that certain information not typically provided by public water systems, such as the type of treatment that the water receives, may be of particular interest to certain bottled water customers. However, the Agency decided to defer consideration of these issues until such time as FDA considers adopting consumer notification regulations for bottled water.

stores in a pamphlet was also not feasible citing concerns over ensuring that the information is current and that the pamphlets are consistently available. Additionally, FDA concluded that the Internet is not appropriate as the sole means of providing information because not all customers may have access to it. Instead, FDA concluded that appropriate and feasible means to inform consumer about their bottled water included:

- Providing on the bottled water label a company contact (with phone number or an address) that would direct customers on how to obtain information;
- A combination approach whereby some quality information would be specified on the label and the remainder of the information would be available through contact with the company; or,
- Distribution of an information package with bulk water deliveries.

In its August 2000 comments on FDA's draft "Feasibility" Study report, IBWA concurred with FDA's findings and noted that existing FDA labeling requirements mandate that the name and place of business of the manufacturer, packer or distributor appear on the label.

Recognizing the importance of providing consumers access to information, the bottled water industry had already incorporated a provision into the IBWA Model Code requiring members to provide information that demonstrates compliance with applicable federal and state Standards of Quality, as well as a contact telephone number on proprietary brand product labels. Thus, bottled water from IBWA members are expected to already be in conformance with FDA's findings. In order to further promote access to this consumer information, in September 2001, IBWA petitioned FDA to mandate that all bottled water products contain a company contact telephone number on the label. IBWA advocated that FDA amend its regulations at 21 C.F.R. §101.5 to specify that:

*In addition to the information required by this section, the label of any bottled water subject to 165.110 shall bear a telephone number that consumers may call to obtain information.*

As noted in its Citizen's Petition, the adoption by FDA of Federal labeling standards would mean the consumer is getting consistent and understandable information.

## **VI. SUMMARY AND CONCLUSION**

The safety of bottled water is ensured through comprehensive regulatory programs at the federal and state level as well as through industry systems that go beyond the minimum standards required by law. At the federal level, bottled water is regulated as a packaged food product by the United States Food and Drug Administration through the Federal Food, Drug, and Cosmetic Act. FDA regulations for bottled water are required to be at least as protective of public health as Environmental Protection Agency regulations for

tap water. Many states have further regulated bottled water, typically through state environmental, food or agricultural agencies.

Over the past several years, FDA has continued to adopt bottled water quality standards. More recently, the Agency has expanded its focus to include guidance and regulations to address the increased security threats.

The safety and high quality of bottled water is further enhanced through the bottled water industry's own programs. These provisions are embodied within the IBWA Model Code and address the protection of bottled water starting with the source water and extending through the product's packaging.

