

FINAL FEDERAL REGULATORY ACTIVITY – (as of December 2004)

US FDA Issue	FDA Rulemaking Dates	FDA Implementation Date	Impact on IBWA Members	IBWA Action	Action to be Taken With Agency(ies)/Timing
<p>NINE CONTAMINANTS SOQs</p>	<p><u>Direct Final Rule:</u> May 11, 1998. FDA amended the bottled water quality standard in 21 CFR 165 by establishing allowable levels for 9 chemical contaminants: antimony, beryllium, cyanide, nickel, thallium, diquat, endoathall, glyphosate, and dioxin.</p> <p><u>Notice:</u> August 6, 1998. Due to receiving significant adverse comments on proposed monitoring requirements for the 9 contaminants, FDA allowed "hammer" to fall. Consequently, as outlined in Notice, bottled water monitoring requirements follow the US EPA monitoring requirements for public water systems.</p>	<p><u>Implementation Date:</u> February 2, 1999.</p> <p><u>Monitoring Guidance:</u> FDA stated in August 1998 Notice that it would issue guidance concerning how to apply EPA's monitoring requirements to bottled water—but did not do so.</p> <p>Consequently, IBWA prepared and submitted to FDA in May 2004 suggested guidance to enable IBWA members to comply with EPA regs.</p> <p>FDA stated in a Sept. 2004 meeting that it had reviewed IBWA's monitoring guidelines for the 9 contaminants, and that it concurs that the proposed monitoring schedule meets regulatory requirements.</p>	<p>EPA's monitoring requirements required four consecutive quarters of testing during the initial three year monitoring cycle (1999-2001).</p> <p>Under EPA's rule, if no detects during the initial three year period, reduced monitoring is allowed during the next three year monitoring cycles (2002-2004, 2005-2008) <u>based on the size of the public water system</u> (>3,300 persons - 2 quarterly samples; <3,300 persons - 1 sample). As the size designation is not applicable to bottled water production, bottlers have no clear direction on how to comply with monitoring requirements.</p>	<p>Given the lack of guidance from FDA on how to apply EPA's 9 Contaminant Rule to bottled water, IBWA developed its own guidance recommendations for members on how to comply with the monitoring requirements. These recommendations were submitted to FDA in May 2004 for the agency review and concurrence.</p> <p>The IBWA Model Code was amended, effective in 2004, that the 4 synthetic organic chemicals (SOCs) be tested once every 3 years in finished product, pending no detection in the first three year monitoring cycle and annually in source water.</p>	<p>None – Completed.</p> <p>In a September 2004 meeting, FDA concurred with IBWA that its members can reduce testing for the four synthetic organic chemicals (diquat, endoathall, glyphosate, dioxin) to once every three years in the event of previous non-detects.</p> <p>IBWA sent letter to FDA commemorating Agency on monitoring requirements.</p>

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<p>LONG TERM 1 ENHANCED SURFACE WATER TREATMENT RULE – LT1ESWTR</p>	<p><u>Final Rule:</u> January 14, 2002. Purpose is to improve control of microbial pathogens, specifically, Cryptosporidium. Applies to systems that serve less than 10,000 and are either surface water or ground water under direct influence of surface water (GWUDI). <u>EPA Implementation/Compliance Date:</u> Rule was effective 30 days after publication (Feb 14, 2002); implementation required 90 days to 3 years after promulgation.</p>	<p><u>FDA Decision Date:</u> Feb. 14, 2002. <u>FDA Implementation Date:</u> Not applicable</p>	<p>May impact bottlers whose source water is surface water or groundwater under the direct influence of surface water.</p>	<p>IBWA sent FDA letter on Sept 9, 2004, confirming position that LT1ESWTR does not apply to bottled water (because LT1ESWTR is enhancement/extension of EPA's Interim Enhancement Surface Water Treatment Rule, which FDA previously ruled was not applicable to bottled water). In Sept. 2004 meeting, FDA concurred with IBWA's position. As such, FDA does not need to issue a Notice in the <u>Federal Register</u>.</p>	<p>None—Completed.</p>

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<p>FILTER BACKWASH RECYCLING RULE – FBRR</p>	<p><u>Final Rule:</u> June 8, 2001. The FBRR requires public water systems using surface water or groundwater under the direct influence of surface water (GWUDI) to recycle spent filter backwash water. <u>EPA Compliance/Implementation Date:</u> June 8, 2004.</p>	<p><u>FDA Decision Date:</u> January 8, 2004. <u>FDA Implementation Date:</u> Not applicable</p>	<p>May impact bottlers whose source water is surface water or groundwater under the direct influence of surface water, use direct or conventional filtration and recycle spent filter backwash.</p>	<p>IBWA sent letter to FDA in October 2003 stating its belief that EPA's Filter Backwash Recycling Rule is not applicable to bottled water and extension of IESWTR. FDA has indicated it is treating Rule as an enhancement of Interim Enhanced Surface Water Treatment Rule (IESWTR), in which FDA formerly ruled (July 5, 2001) that a standard of quality regulation for control of Cryptosporidium in bottled water is not necessary. As such, FDA will not issue a Notice that the Filter Backwash Recycling Rule does not apply to bottled water. In July 2004, IBWA confirmed with Counsel that FDA's/IBWA's opinion that FDA does not need to issue further Notice is correct.</p>	<p>None—Completed.</p>

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<p>STAGE 1 D/DBP RULE (Bromate) (Final Regulation)</p> <p>FDA Direct Final Rule on March 28, 2001 and July 5, 2001. Effective Date January 1, 2002.</p>	<p><u>Direct Final Rule:</u> March 28, 2001 and July 5, 2001.</p> <p><u>Implementation Date:</u> January 1, 2002.</p> <p>On July 5, 2001 FDA published a <i>Federal Register</i> Notice that announced that the Agency decided it would not take enforcement action against bottled water products already in interstate commerce before January 1, 2002 provided such products are considered safe.</p>	<p><u>FDA Decision Date:</u> July 1, 2001.</p> <p><u>FDA Implementation Date:</u> January 1, 2002.</p>	<p>D/DBP rule can impact source water with bromide ion that is treated with ozone.</p>	<p>Continue DBP Task Force activities to study impact of treatment processes on formation of bromate and investigate preventive measures.</p> <p>IBWA Model Code amended to include quarterly bromide, bromate testing in 2001. In 2002, Model Code amended to incorporate FDA Quality Standards and monitoring (annual if necessary).</p> <p>Monitor research on bromate being conducted by EPA, International Ozone Association, and American Water Works Association.</p> <p>In 2002, IBWA received letter from FDA authorizing the use of C)2 for minimal treatment to meet bromate SOQ.</p>	<p>Continue to meet with FDA to convey IBWA's position on the FDA Disinfection Byproducts Rule. Keep FDA updated on any new developments.</p>

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<p>INTERIM ENHANCED SURFACE WATER TREATMENT RULE (IESWTR)</p> <p>FDA Direct Final Rule on July 5, 2001.</p>	<p>EPA regulation in place for Public Water Systems, effective January 1, 2002.</p> <p>On July 5, 2001 FDA announced in a <i>Federal Register</i> notice that it does not need to issue a standard of quality regulation for the control of Cryptosporidium because it would not be found in groundwater used for bottled water. Public water systems serving at least 10,000 people or more, using surface water or ground water under the direct influence or surface water, must comply with EPA's IESWTR.</p>	<p>Not applicable.</p>	<p>May impact bottlers whose source water is surface water or groundwater under the direct influence of surface water.</p>	<p>Monitor any adverse comments in response to FDA's action. No comments in Docket (01N-0280) as of October 2003.</p>	<p>Continue to meet with FDA to discuss position and to convey responses to any adverse comments, if necessary.</p>



International Bottled Water Association

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<p>FDA DRAFT FEASIBILITY STUDY (Consumer Confidence Reporting)- Final Report released on August 25, 2000.</p> <p>The FDA published, “a final study on the feasibility of appropriate methods, in any, of informing customers of the content of bottled water.” This study examined whether bottled water companies should be required to issue similar reports to consumer confidence reports required by EPA of public water systems (PWSs).</p>	<p>Final Report: August 25, 2000.</p>	<p>FDA missed the statutory deadline for issuing the final report (February 1999), but released it 16 months later in August 2000.</p>	<p>FDA did not propose new labeling requirements in the study, but suggested that a future rulemaking could address such issues as requiring type of treatment on the label.</p> <p>Water quality reporting will increasingly become a high visibility issue in light of an alert issued by the EPA Office of Regulatory Enforcement describing requirements for community water systems to provide annual Consumer Confidence Reports (CCR) by July 1, 2001. The alert also notes that EPA and states have been taking enforcement actions against public water systems that do not comply with CCR requirements.</p>	<p>Briefed Congressional allies on the Study. IBWA will monitor for the prospect of any federal legislative action. In October 1999, water utilities were required to send out their first consumer confidence report. IBWA members are strongly encouraged to utilize the IBWA Water Quality Report Template. Monitor any adverse comments in response to FDA’s action. No new comments for Docket (97N-0436).</p>	<p>In a future rulemaking FDA could propose new labeling requirements. IBWA will continue to monitor and communicate with FDA on this issue. IBWA will continue to monitor any legislative developments in this area as well.</p>

**International Bottled Water Association
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<p>RADIONUCLIDES – (Final Regulation) On December 7, 2000 EPA issued final rule for uranium and revisions to monitoring requirements for combined radium 226/228, gross alpha and beta particle and photon radioactivity.</p> <p>On March 3, 2003, FDA published in the <i>Federal Register</i> an interim final regulation on bottled water quality standard regulations for establishment of an allowable level of 30 ug/L for the substance uranium and new monitoring requirements for radium 226/228.</p> <p>FDA Direct Final Rule on June 9, 2003 for uranium standard.</p>	<p>Final Rule: June 9, 2003. Implementation Date: Uranium final SOQ as of December 8, 2003. Revised monitoring requirements for others by December 8, 2003.</p>	<p>FDA Implementation Date: December 8, 2003.</p>	<p>Bottled water manufacturers would be required to monitor their finished bottled water products for gross alpha, gross beta, radium 226/228, and uranium at least once each year in each product type under the current good manufacturing practice (CGMP) regulations for bottled water. Bottlers would also be required to monitor their non-public water system source water for uranium as often as necessary, but at least once every four years unless they meet the criteria for source water monitoring exemptions under the CGMP regulations. FDA will retain the existing standards of quality for combined radium 226/228, gross alpha particle radioactivity, and beta particle and photon radioactivity.</p>	<p>IBWA advised members of new monitoring requirements and amended Model Code Appendix A.</p>	<p>Inform FDA that IBWA has amended the Model Code to include radionuclides.</p>

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US EPA Issue & Proposal Date	EPA Final/Implementation Date	FDA Statutory Deadline	Impact on IBWA Members	IBWA Action	Action to be Taken With Agency(ies)/Timing
<p>UNREGULATED CONTAMINANT MONITORING RULE – (Final Regulation)</p>	<p><u>Final Rule:</u> September 17, 1999. <u>Implementation Date:</u> January 1, 2001 for monitoring to commence. On October 29, 2002, EPA approved the analytical method 1605 and an associated Minimum Reporting Level (MRL) to support the unregulated contaminant monitoring regulation's (UCMR) List 2 Aeromonas monitoring.</p>	<p>No need to FDA to take action since it is not a standard.</p>	<p>Monitor proposed list of unregulated contaminants and any proposed analytical methods and any regulatory testing protocols.</p>	<p>Since the unregulated monitoring program is not a formal drinking water standard, there is no need to FDA to adopt a regulation for bottled water for these substances. Furthermore, current science does not support regulation of the EPA unregulated substances in drinking water or bottled water at this time. Virus/Microbial Subcommittee will review additions when proposal is released. Subcommittee will follow action on EPA proposed method 1605 for Aeromonas.</p>	<p>FDA was briefed on IBWA's position paper on December 12, 2001 by IBWA representatives. FDA verbally agrees with IBWA's position.</p>
<p>SULFATE- EPA decision not to regulate on July 18, 2003.</p>	<p><u>Final Rule:</u> July 18, 2003 to not regulate sulfate. <u>Implementation Date:</u> Not applicable.</p>	<p>Not applicable.</p>	<p>Possible impact on some mineral waters that contain sulfates.</p>	<p>Monitor any future EPA activity.</p>	<p>Monitor.</p>