



STATUS OF PENDING FEDERAL REGULATORY ACTIVITY - 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>PERCHLORATE</p>	<p>No rule proposed to date.</p> <p>FDA released a report titled "Exploratory Data on Perchlorate in Food" on 11/26/04. Results were posted for lettuce, milk, and bottled water. Of 51 bottled water samples analyzed 2 samples contained <1 ppb of perchlorate.</p> <p>Results of this survey may be used to establish regulatory standards for perchlorate in food, including a possible SOQ for perchlorate in bottled water. Possible timing of a proposed rule is early 2005.</p> <p>There is no indication of what FDA could set an SOQ at, given the range in health studies.</p>	<p>None to date</p>	<p>Impact is minimal. 2 of 51 samples analyzed contained <1 ppb of perchlorate.</p>	<p>In November 2003 IBWA provided information to FDA on industry detection limits for perchlorate.</p> <p>IBWA formed the Perchlorate Task Force Chaired by Andy Eaton to follow this issue.</p> <p>In August of 2004, IBWA issued a Technical Bulletin to members encouraging them to consider testing for perchlorate at new, lower levels of detection.</p> <p>IBWA Communications dept. has prepared position paper to respond to FDA's release of test results.</p>	<p>IBWA to interact closely with FDA on possibly development of a SOQ for perchlorate.</p>



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<p>BIOTERRORISM – Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) <u>Sections:</u> Food Facility Registration Records Maintenance Prior Notice of Imported Foods</p>	<p><u>Proposed Rules:</u> Registration of Food Facilities and Prior Notice of Imported Foods Proposed Rules published Feb. 3, 2003. <u>Proposed Rule:</u> Establishment and Maintenance of Records Proposed Rule published May 9, 2003. <u>Interim Final Rules:</u> Registration of Food Facilities & Prior Notice of Imported Foods Interim Final Rules published on October 10, 2003. <u>Final Rules:</u> Registration of Food Facilities & Prior Notice of Imported Foods Final Rule expected in March 2005. <u>Final Rule:</u> Records Maintenance Rule finalized on December 9, 2004.</p>	<p>Deadline for Registration of Food Facilities was Dec. 12, 2003. Deadline for implementation of Prior Notice of Imported Foods was Dec. 12, 2003. For Records Maintenance – scalable implementation date of 6, 12, or 18 months, depending on facility size – Compliance dates: 500+ employees – 12/9/05 11-499 employees – 6/9/06 1-10 employees – 12/9/06.</p>	<p>Bottled water companies and suppliers to the bottled water industry are responsible for compliance with the Bioterrorism Act and for security of their products and facilities. All bottled water facilities had to register with FDA by December 12, 2003. Failure to register is prohibited act. For foreign food facilities, failure to register will result in refused entry. Failure to provide adequate prior notice of importation of food products will result in refused entry. Bottled water facilities must implement records maintenance in accordance with final rule.</p>	<p>IBWA provided educational seminars for members on Bio-terrorism rules in 2003 & 2004. IBWA Submitted Comments to FDA on: --Proposed Facility Registration and Prior Notice Rules (April 4, 2003) --Proposed Record Maintenance Rule (July 8, 2003) --Interim Final Facility Registration and Prior Notice Rules (Dec. 10, 2003, Dec. 23, 2003, & May 14, 2004) In June 2004, IBWA formed Bottled Water Security Task Force. Task Force is working with FDA on bottled water threat assessment (CARVER & Shock). Results can be used to identify countermeasures to reduce security threats. IBWA to provide seminars on CARVER and records maintenance in 2005.</p>	<p>IBWA will coordinate activities with FDA and the IBWA Bottled Water Security Task Force on a threat assessment. IBWA will review and submit comments to FDA (if necessary) on Records Maintenance Interim Final Rule when released. Threat assessment results will be used to develop educational materials for IBWA members. Seminars will given at State and Regional associations meetings in 2005.</p>



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<p>ARSENIC</p>	<p><u>Final Rule:</u> On January 22, 2001 EPA promulgated revised NPDWR for arsenic lowering the MCL from 50 ppb to 10 ppb.</p> <p><u>EPA Implementation/Compliance Date:</u> January 23, 2006.</p>	<p><u>FDA Decision Date:</u> No later than July 23, 2005, FDA must propose arsenic regulation for bottled water (or find that EPA's regulation is not applicable).</p> <p><u>FDA Proposed Rule:</u> On December 2, 2004 FDA Proposed to amend the bottled water quality standard regulations by revisiting the existing allowable level for arsenic from 50 ppb to 10 ppb.</p> <p>Written or electronic comments on this proposal are due by January 31, 2005.</p>	<p>As per the Model Code, IBWA members currently must already meet the SOQ of 10 ppb.</p> <p>Bottled water manufacturers would be required to monitor their finished product for arsenic at least once a year. In addition, they would also be required to monitor their source water as often as necessary, but at least once a year unless they meet the criteria for the source water monitoring exemptions under the CGMP regulations.</p>	<p>IBWA has urged FDA to lower the current arsenic SOQ of 50 ppb for bottled water to 10 ppb as soon as possible.</p> <p>In 2002, IBWA amended the Model Code and established an SOQ of 10 ppb for arsenic.</p> <p>In response to an inquiry from FDA in February 2004, IBWA responded negatively to FDA's consideration of a SOQ of less than 10 ppb for arsenic and provided the agency with new health studies of arsenic effects.</p>	<p>IBWA to prepare and submit comments to FDA in support of proposed rule.</p>



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<p>GROUND WATER RULE - GWR (formerly called Groundwater Disinfection Rule)</p>	<p><u>Proposed Rule:</u> May 10, 2000. Sets standards and disinfection requirements for public water systems that are served solely by ground water; or distribute ground water not treated to 4-log virus inactivation/removal (and considered at risk for fecal contamination). <u>Final Rule:</u> Delayed. EPA working to address stakeholder concerns. Currently expected early 2005 (must be issued no later than final Stage 2 D/DBPR) <u>EPA Implementation/Compliance Date:</u> 3 years from final rule (approx. Feb. 2008), but could be 5 years (February 2009) if necessary for capital improvements. (EPA Rule Manger, Crystal Rogers)</p>	<p><u>FDA Decision/Proposed Rule Date:</u> Required by July 2007. <u>FDA Implementation Date:</u> Not likely before February 2008.</p>	<p>Impacts to IBWA members would be determined by FDA's interpretation of the EPA rule. EPA's proposed rule requires monthly testing of sensitive or untreated source waters for <i>E.coli</i>, enterococci, or coliphage. Also must test for one of these if have a positive total coliform.</p>	<p>In Feb. 1999, IBWA submitted comments to EPA on the Preliminary Draft of Proposed Rule. IBWA participated in meetings with AWWA, ASDWA, and others on the proposed EPA rule.</p>	<p>IBWA will review the final EPA rule when it comes out in early 2005 and will prepare and submit comments/recommendations to FDA for its companion rule. IBWA will urge FDA to take action on its decision/proposed rule before the "hammer" provision deadline of 180 days after effective date of EPA regulation. IBWA will continue to meet with FDA to discuss how IBWA members might be impacted and urge FDA to promulgate a timely companion regulation.</p>



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<p>STAGE 2 DISINFECTION/DIS-INFECTION BY-PRODUCTS RULE</p> <p>STAGE 2 D/DBPR</p>	<p><u>Proposed Rule:</u> August 18, 2003. Would set MCLs of 80 ppb for TTHMs and 60 ppb for 5 haloacetic acids (HAA5).</p> <p><u>Final Rule:</u> Expected by Summer 2005 Rule Manager : Tom Grubbs 202-564-5262</p> <p><u>EPA Compliance Date:</u> 6 years after promulgation of Final Rule for large systems, 7 years for small systems.</p>	<p><u>FDA Decision/Proposed Rule Date:</u> Required by Jan./Feb 2011.</p> <p><u>FDA Implementation Date:</u> Not likely before June/July 2011.</p>	<p>EPA's MCLs for drinking water have not changed from Stage 1 DBP rule, thus FDA SOQs would not change.</p> <p>(FDA's Final Rule for Stage 1 D/DBP's was published in March 2001 and established allowable levels of DBPs in bottled water.)</p>	<p>IBWA has called FDA's attention to this rule during past meetings & again discussed during Sept. 2004 meeting.</p>	<p>Monitor EPA progress on developing Final Rule.</p> <p>IBWA will review EPA's Final Rule and submit comments to FDA on its applicability to bottled water.</p>
<p>LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE – LT2ESWTR</p>	<p><u>Proposed Rule:</u> August 11, 2003. Requires additional removal of <i>Cryptosporidium</i>.</p> <p><u>Final Rule:</u> Expected by June/July 2005</p> <p><u>EPA Implementation/Compliance Date:</u> 6 years (72 months) after promulgation of Final Rule for large systems, 8.5 years (102 months) for small systems.</p>	<p><u>FDA Decision Date:</u> Required by Jan/Feb 2011</p> <p><u>FDA Implementation Date:</u> Not likely before June/July 2011.</p>	<p>May impact bottlers whose source water is groundwater under the direct influence of surface water.</p>	<p>During an October 2003 meeting, IBWA discussed with FDA the association's position that, similarly to the IESWTR, this rule is not applicable to bottled water.</p>	<p>Continue to monitor EPA progress on developing a Final Rule.</p> <p>Keep FDA informed of EPA activities and work with agency to urge them to take same position as on IESWTR--that this rule is not applicable to bottled water.</p>



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<p>RADON RULE</p>	<p><u>Proposed Rule:</u> Nov. 2, 1999. Proposed MCL is 300 pCi/L, proposed AMCL is 4,000 pCi/L.</p> <p><u>Final Rule:</u> Delayed until 2006 or 2007 (or even later); legislative activity could result in further changes in rule.</p> <p><u>EPA Implementation/Compliance Date:</u> Unknown.</p>	<p><u>FDA Decision Date:</u> Not likely before June 2007.</p> <p><u>FDA Implementation Date:</u> Unknown</p>	<p>A 300 pCi/L primary MCL has been proposed. Some bottlers would have to treat their source waters to meet this level if established as the SOQ. An alternative MCL for water utilities of 4,000 pCi/L would be allowed in those states that have prescriptive multimedia programs, but FDA would likely require bottlers to meet a 300 pCi/L standard.</p>	<p>The EPA proposal has been reviewed by a Task Force of the IBWA Technical Committee. Legislative activity is being tracked.</p> <p>IBWA hired an independent scientific consultant from Johns Hopkins University to evaluate whether the proposed radon MCL is relevant from a technical standpoint for bottled water. Final report was submitted to IBWA and is under review by IBWA technical staff and members.</p>	<p>Meet with FDA to discuss possible impacts on IBWA members from final rule.</p>



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US FDA Issue	EPA & FDA Rulemaking Dates	FDA Implementation Dates	Impact on IBWA Members	IBWA Action	Action to be Taken With Agency(ies)/Timing
<p>TOTAL COLIFORM RULE – TCR</p>	<p>EPA: <u>Final Rule:</u> 1989</p> <p><u>Notice:</u> July 18, 2003, EPA stated in <i>Federal Register</i> they will review and revise its Total Coliform Rule.</p> <p><u>Revised Rule:</u> Proposed -- June 2006. Final – TBD, approx. date of June 2008</p> <p>FDA: <u>Proposed Rule:</u> October 6, 1993. Did not recognize need for confirmation testing.</p> <p>FDA has withdrawn its 1993 proposed regulation and announced its intention to revise the current total coliform standard to be more comparable to EPA's total coliform standard for public drinking water.</p> <p><u>FDA Revised Rule:</u> Sometime after estimated EPA Final Rule date of June 2008.</p>	<p>FDA will follow EPA's revisions and timetable for the Total Coliform Rule.</p>	<p>Without a strict FDA rule in place, IBWA members remain vulnerable to public criticism (e.g., NRDC Report) that the bottled water industry is less regulated than tap water. The IBWA Model Code has a zero tolerance standard for total coliform.</p>	<p>IBWA adopted a Total Coliform/E. coli SOQ in Nov. 1999.</p> <p>IBWA has urged FDA to propose and adopt expeditiously a microbiological standard similar to that adopted by IBWA, the WHO, and Codex.</p> <p>On October 6, 2003, FDA was briefed on IBWA's position on the issuance of a total coliform rule. IBWA asked FDA to issue a new proposal to include a microbiological standard similar to that adopted by IBWA in its Model Code. FDA stated that it will wait until EPA takes action on revising its TCR.</p> <p>In Sept. 2004 meeting with FDA, IBWA urged FDA to react quickly once EPA issues its Final revised Rule on total coliform.</p>	<p>Continue to monitor EPA activities on revised Total Coliform Rules.</p> <p>IBWA will, as EPA develops revisions to the MCL for total coliform, keep FDA informed about EPA action and provide recommendations to FDA on how to apply EPA provisions to bottled water.</p>



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<p>CONTAMINANT CANDIDATE LIST - CCL1 & CCL2 (See Appendix A)</p>	<p><u>CCL1</u>: Published March 1998, listed 60 contaminants.</p> <p><u>CCL1 Final Determinations</u>: July 18, 2003. EPA determined no regulatory action needed for: Acanthamoeba, aldrin, dieldrin, hexachloro-butadiene, manganese, metribuzin, naphthalene, sodium, and sulfate.</p> <p><u>CCL2</u>: Draft list published April 2, 2004. Lists 42 chemicals and 9 microbiological contaminants. Final CCL2 expected early 2005.</p> <p><u>CCL2 Determinations</u>: Preliminary determinations expected August 2005; final regulatory determinations for at least 5 CCL2 contaminants due Aug. 2006.</p> <p><u>Draft CCL3</u>: anticipated Feb. 2007</p>	<p>Not applicable since EPA does not establish quality standards under this rule.</p>	<p>Depends on what CCL contaminants EPA decides to regulate.</p> <p>14 CCL chemical contaminants are being considered by determination/regulation by EPA including MTBE, perchlorate, boron, & vanadium</p>	<p>Monitored EPA regulatory determinations on CCL contaminants, including EPA development of draft microbial risk assessment guidelines.</p> <p>IBWA Virus/Microbial Committee reviewed microbial contaminant candidates listed on CCL2 for possible concerns regarding regulation by FDA.</p>	<p>Review contaminant candidates with FDA in future meetings.</p>



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OSHA Issue	OSHA Rulemaking Dates	OSHA Implementation Date	Impact on IBWA Members	IBWA Action	Action to be Taken With Agency(ies)/Timing
<p>ERGONOMICS - In March, 2001 the Congress passed a joint resolution of the disapproval of the ergonomics rule. The President approved.</p> <p>OSHA will be issuing voluntary industry and task specific guidelines, they have started with the retail food and nursing home industries. They will rely on current law and enforcement authority.</p> <p>OSHA announced April 14, 2004 that they are targeting 4,000 high hazard worksites. They also intend on inspecting 200 industry worksites with above average injury rates.</p>	<p>OSHA will be issuing voluntary industry and task specific guidelines, they have started with the retail food and nursing home industries. They will rely on current law and enforcement authority.</p> <p>OSHA announced April 14, 2004 that they are targeting 4,000 high hazard worksites. They also intend on inspecting 200 industry worksites with above average injury rates.</p>	<p>None.</p>	<p>Disapproved rule would have required bottlers and distributors to implement a 6-part ergonomics program to ensure that the workplace and workers' specific duties will not cause musculo-skeletal disorders.</p> <p>The draft voluntary guidelines address heavy lifting and other issues which could potentially impact the bottled water industry.</p> <p>In addition, ANSI and ISO are developing ergonomic standards for industry. They are ANSI Z-365 and Z-10 domestically, and ISO 18001 OHSMS in the international market.</p>	<p>IBWA filed comments with OSHA on February 1, 2000. OSHA will be issuing voluntary industry and task specific guidelines. They have started with the retail food and nursing home industries. They will rely on current law and enforcement authority.</p>	<p>Monitor OSHA and standard setting organizations for activity on ergonomics.</p> <p>IBWA is a member of the National Ergonomics Coalition.</p>

Appendix A
U.S. Environmental Protection Agency's (EPA)
Draft Drinking Water Contaminant Candidate List 2 – CCL2 (April 2, 2004)

Microbiological contaminant candidates:

- Adenoviruses
- Aeromonas hydrophila
- Caliciviruses
- Coxsackieviruses
- Cyanobacteria (blue-green algae), other freshwater algae, and their toxins
- Echoviruses
- Helicobacter pylori
- Microsporidia (Enterocytozoon & Septata)
- Mycobacterium avium intracellulare (MAC)

Chemical contaminants candidates:

- | | | |
|--|--------------------------------------|-------------------------------------|
| 1, 1, 1, 2-tetrachloroethane | Aluminum | Methyl-t-butyl ether (MTBE) |
| 1, 2, 4-trimethylbenzene | Boron | Metolachlor |
| 1, 1-dichloroethane | Bromobenzene | Molinate |
| 1, 1-dichloropropene | DCPA mono-acid degradate | Nitrobenzene |
| 1, 2-diphenylhydrazine | DCPA di-acid degradate | Organotins |
| 1, 3-dichloropropane | DDE | Perchlorate |
| 1, 3-dichloropropene | Diazinon | Prometon |
| 2, 4, 6-trichlorophenol | Disulfoton. | RDX |
| 2, 2-dichloropropane | Diuron. | Terbacil |
| 2, 4-dichlorophenol | EPTC (s-ethyl-dipropylthiocarbamate) | Terbufos |
| 2, 4-dinitrophenol | Fonofos | Triazines & degradation products of |
| 2, 4-dinitrotoluene | p-Isopropyltoluene (p-cymene) | Triazines |
| 2, 6-dinitrotoluene | Linuron | Vanadium |
| 2-methyl-Phenol (o-cresol) | Manganese | |
| Acetochlor | Methyl bromide | |
| Alachlor ESA & other acetanilide
pesticide degradation products | | |