Patrick Donoho <pdonoho@bottiedwater.org>
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Record Type: Record

To: John F. Morrall III/OMB/EOP@EOP

cc: Joe Doss <jdoss@bottledwater.org>
Subject: International Bottled Water Association's Comments on Draft Report

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Dear Mr. Morrall:

Attached is a copy of the international Bottled Water Association's (IBWA) comments on the Office of Management and Budget's (OMB) Draft Report to Congress on the Costs and Benefits of Federal Regulation (the Report) for which comments were requested March 28, 2002, in the Federal Register. The focus of IBWA's comments are on Chapter IV of the Report, which solicits recommendations from the public on reform of Federal rules.

The four suggested bottled water regulations for review are attached in the suggested format. IBWA's comments for modifications of bottled water regulations address four changes to the Standards of Quality as established by Food and Drug Administration (FDA). One of the recommendations is for a change to the current frequency for testing bottled water for nine specific compounds. The other three recommendations are for new regulations for specific standards of quality (SOQ) levels for bottled water. FDA is aware of IBWA's position on these issues. The support of OMB in establishing the standards, as priorities will assist in strengthening the publics trust in the safety and quality of bottled water.

A hard copy of the letter and enclosures will follow. IBWA welcomes the opportunity to provide any additional information on these issues if needed. IBWA believes these recommendations meet the criteria established in the request for comments and appreciates your attention to these matters. If you have any questions, please do not hesitate to contact IBWA.

Sincerely,

Patrick Donoho
Vice President, Government Relations
IBWA
1700 Diagonal Road, Suite 650
Alexandria, VA 22314
(703) 683-5213 ext. 108
(703) 683-4074 (fax)

- att1.htm

 - PD-OMB letter-final-email.doc

 - Aresenic-final OIRA.doc

 - Uranium-OMB-final.doc

 - Nine contaminants - OIRA - final.doc

 - PD-OIRA-Total Coliform-final.doc

 - Appendix C.doc

IBWA
International Bottled Water Association

1700 Diagonal Road, Suite 650
Alexandria, VA 22314
Phone: 703-683-5213
Fax: 703-683-4074

May 28,2002

Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB
Room 10235
725 17th Street, N.W.
Washington, D.C. 20503

Dear Mr. Morrall:

The International Bottled Water Association (IBWA) appreciates the opportunity to provide comments on the Office of Management and Budget's (OMB) Draft Report to Congress on the Costs and Benefits of Federal Regulation (the Report). The focus of these comments will be on Chapter IV of the Report, which solicits recommendations from the public on reform of the Federal rules.

IBWA is the trade association representing the bottled water industry. Founded in 1958, IBWA member companies account for more than 80 percent of all bottled water sales in the U.S. The association membership includes domestic and international bottlers, distributors, and suppliers. Of the over 260 bottler members of IBWA, the vast majority are small, family-owned businesses. Some of the members are being operated by the second or third generation of the founders.

Background

Bottled water is fully regulated as a packaged food product by the U.S. Food and Drug Administration **(FDA)** and bound by FDA's standards of identity, safety, inspection, enforcement and labeling requirements. In addition to these types of regulations for bottled water, FDA regulations establish standards of quality (SOQ) for bottled water. The SOQ's provide health-based limits for compounds in bottled water, similar to the standards for drinking water in public water systems. In fact, the Safe Drinking Water Act Amendments of 1996 (SDWA) included a provision that is commonly referred to as the "Hammer Provision." The Hammer Provision provides that the Secretary of the U.S. Department of Health and Human Services (HHS) shall consult with the Administrator of the U.S. Environmental Protection Agency (EPA) in regard to any EPA-proposed changes to the national primary drinking water regulations for public water supplies. Within 180 days of the implementation of such EPA regulations, the Secretary must either promulgate amendments to the FDA regulations applicable to bottled drinking water or publish in the *Federal Register* reasons for not making such amendments. Otherwise, the EPA standards will apply to bottled water.

In addition, most states have established bottled water regulations. Many states adopt the FDA standards of quality and the definitions for bottled water. Therefore, FDA regulatory changes also have direct impact on state regulations for bottled water.

Recommendations for Chapter IV of the Report:

IBWA's comments for modifications of bottled water regulations address four suggested changes to the Standards of Quality as established by FDA. One of the recommendations is for a change to the current frequency for testing bottled water for nine specific compounds. The other three recommendations are for new regulations for specific SOQ's levels for bottled water. FDA is aware of IBWA's position on these issues.

Enclosed are the recommendations in the format requested in the Notice for Public Comment. The following is a brief summary of the four recommendations being submitted for your consideration and assistance in promulgating modifications to bottled water regulations. Consumers of bottled water will be better protected with the adoption of new regulations for total coliform, arsenic, and radionuclides. In addition, the recommended changes to the frequency of testing for nine compunds will ease the regulatory burden on bottled water producers without compromising bottled water safety or quality.

1. Total coliform - IBWA is recommending the adoption of a total colifom standard for bottled water of "No *Escherichia coli* detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by retesting." FDA began the rulemaking process for total coliform in 1993 and has included it in years past as one of the B priorities by the FDA's Center for Food Safety and Nutrition (CFSN) in their annual notice. However, it was not included as a priority for CFSN this year. By establishing the SOQ for total coliform, it strengthens the microbiological standard for bottled water, a key pillar in consumers' trust in the product.

2. Arsenic – IBWA is recommending that the FDA initiate formal rule making to reduce the bottled water SOQ for arsenic from the current level of 50 ppb to 10 ppb, effective in 2003. The EPA has recently promulgated a standard for public drinking water of 10 ppb that will become effective in 2006. The IBWA recommendation essentially speeds up the application of an arsenic standard for bottled water. Because of the "Hammer Provision" of the SDWA Amendments of 1996, FDA is required to address a bottled water standard by July 2005.

3. Radionuclides – **IBWA is** recommending that the **FDA** immediately establish a SOQ for uranium at 30 µg/L and maintain its current standard for the other regulated radionuclides. In December 2000, the EPA published a final National Primary Drinking Water Regulation (NPDWR)

for radionuclides. The standard for uranium is set at 30 µg/L. In addition, the EPA regulation prescribes a monitoring scheme for all regulated radionuclides. By expanding the radionuclide regulation to uranium, FDA will also apply the annual monitoring and compliance determinations to uranium.

4. Nine Compounds Monitoring Guidance – IBWA is recommending that FDA formally establish an annual frequency of testing for nine specific compounds. Specifically, FDA should either: 1) modify the monitoring requirements for the four specific contaminants (diquat, endothall, gyphosate, and dioxin) from 6 samples every three years to one sample annually, in conformance with the remainder of FDA's good manufacturing practice requirements for bottled water; or 2) release a guidance document outlining FDA's requirements for all of the nine compounds, as suggested in the agency's notice dated August 6, 1998, published in the *Federal Register.* The EPA version of the nine compounds rule required that public water systems monitor for the four contaminants listed above for four consecutive quarters once every three years. By allowing the "Hammer Provision" of the Safe Drinking Water Act Amendments of 1996 to take effect, the same monitoring frequency was required for bottled water. However, the EPA standard provides for reduced monitoring (annual) when it is proven that the compounds are not found in a specific public water system. As of December 31, 2001, after three years of monitoring in accordance with the August 6, 1998 notice, none of the four contaminants have been detected in IBWA members' bottled water products. This demonstrates that continued monitoring, although costly, will exhibit no further benefit to the protection of public health. IBWA is simply requesting the monitoring tests be conducted annually.

The first three recommendations will improve the quality of bottled water within the United States. It will also help ensure that the public health is protected commensurate with the current scientific knowledge on the subjects. Two of these three recommendations (2 and 3) are currently listed as "B" priorities for the CFSN in 2002. Given the public health issue involved and the industry consensus on the approach, a higher priority and/or achievement of the priority should be able to be accomplished this year.

The fourth recommendation will both reduce the costs to the industry without health or safety concerns and reduce the paperwork for state regulators and industry. Under the current regulatory requirements, bottled water producers must test for the contaminants six times over a three-year period. IBWA's recommendation will reduce that number by one half at a cost savings of over one million dollars to the industry, without any drop in consumer protection.

IBWA welcomes the opportunity to provide any additional information on these issues if needed. IBWA believes these recommendations meet the criteria established in the request for comments and appreciates your attention to these matters. IBWA has

made these suggestions to **FDA** directly, and, in the case of total coliform, has been urging the **FDA** to promulgate a standard for a number of years. The support of OMB in establishing the standards, as priorities will assist in strengthening the publics trust in the safety and quality of bottled water.

If you have any questions, please do not hesitate to contact Patrick Donoho, Vice President of Government Relations, at: pdonoho@bottledwater.org; or me at: jdoss@bottledwater.org.

Sincerely,

Joseph Doss
President

Enc. (5)

IBWA Recommendations for Regulatory Improvement

Name of Regulation: Standard of Chemical Quality – Arsenic

Regulating Agency: The U.S. Food and Drug Administration

Citation: 21 CFR 165.110(b)(4)

Authority: 21 USC 349; 21 USC 321(f); 21 USC 342 and 343

Description of the Problem:

The U.S. Environmental Protection Agency (EPA) promulgated a revised National Primary Drinking Water Regulation (NPDWR) for arsenic that lowered the maximum contaminant level (MCL) from 50 ppb to 10 ppb on January 22, 2001 (66 *Federal Register* 6976) for all public drinking water systems. On January 23, 2006, the regulation will be implemented for public water systems. The regulation, not only sets a MCL of 10 ppb for arsenic, but also establishes monitoring requirements and approaches to demonstrate compliance.

Under 21 USC 349, the Secretary of Health and Human Services is required to review any regulation of a drinking water contaminant by the EPA and rule on its applicability to bottled water 180 days before the implementation of the standard by **EPA.**

Proposed Solution:

The International Bottled Water Association (IBWA) recommends accelerating the adoption of an arsenic standard for bottled water. Specifically, FDA is urged to adopt a standard of chemical quality of 10 ppb for bottled water with an effective date as early as possible. In addition, FDA should also maintain the same annual monitoring frequency and the process for compliance determinations that are currently in place for bottled water under 21 CFR 129.80(g)(2).

The procedure to accomplish the revised arsenic standard for bottled water will be to revise the current standard of 50 ppb through rule making by the FDA.

Estimate of Economic Impact:

IBWA estimates that there will be minimal economic impact on the bottled water industry by revising the standard of chemical quality for arsenic to 10 ppb. IBWA represents about 80% of the bottled water industry. The members of IBWA must

adhere to a the IBWA Model Code that includes additional industry based standards of quality (SOQ) for bottled water. In addition, the members must submit to annual unannounced inspections by an independent third party and perform monitoring and testing for conformance to the IBWA Model Code SOQ's. IBWA has lowered the Model Code SOQ for arsenic to 10 ppb with an effective date of January 1, 2002.

A FDA regulation will also continue the monitoring system for arsenic that is protective of the public health and not impose new systems for monitoring and compliance on the bottled water industry.

IBWA Recommendations for Regulatory Improvement

Name of Regulation: Standard of Chemical Quality – Uranium

Regulating Agency: The U. S. Food and Drug Administration

Citation: 21 CFR 165.110(b)(5)(i)

Authority: 21 USC 349; 21 USC 342; 21 USC 343

Description of the Problem:

The U.S. Environmental Protection Agency (EPA) promulgated a final National Primary Drinking Water Regulation (NPDWR) for radionuclides that include maximum contaminant levels (MCL) for combined radium-226/-228, (adjusted) gross alpha, beta particle and photon activity, and uranium on December 7, 2000. (65 *Fed. Reg.* 76708) The compliance date for the regulation is December 7, 2003. This standard only applies to public drinking water systems.

The EPA radionuclides rule established an MCL for uranium at 30 µg/L. Additionally, the rule reaffirmed the following MCLs adopted by the EPA in 1976:

- Combined Radium-226/228 - 5 pCi/L;
- Adjusted Gross Alpha - 15 pCi/L, not including radon or uranium; and,
- Beta Particle and Photon Radioactivity - 4 millirems/year.

The EPA rule sets out a monitoring scheme for all of the regulated radionuclides. The regulations direct that the results from an initial round of monitoring determine the frequency for additional rounds of monitoring. For example, public water systems with less than detectable levels are permitted to analyze once every 9 years, systems with less than one half the MCL are required to monitor every 6 years and systems with greater than one half the MCL are required to analyze every three years.

FDA has already issued a standard of quality for bottled water for each of these radionuclides, except uranium. These standards are the same as the EPA standards [21 CFR§165.110(b)(5)]. However, the FDA annual monitoring and compliance determination provisions apply to these standards, but not to uranium because of the lack of a standard for bottled water.

Under 21 USC 349, the Secretary of U.S. Department of Health and Human Services (HHS) is required to review any regulation of a drinking water contaminant by the EPA and rule on its applicability to bottled water 180 days before the implementation of the standard by EPA. Without the adoption of a standard of radiological quality for uranium by FDA, bottled water producers will be subject to a new system for testing, monitoring and analysis for uranium that is substantially different from the current regulated radionuclides for bottled water.

Proposed Solution:

The International Bottled Water Association (IBWA) recommends that FDA adopt a new 30 µg/L standard of radiological quality for uranium promptly. FDA should establish a new regulation for uranium through procedures for rule making within FDA and the Federal government. In promulgating this standard, FDA should maintain the current annual monitoring and compliance determination provisions that are currently in place for the other radionuclides [21 CFR §129.80 (g)(2)]. The FDA annual monitoring scheme for radionuclides has worked well for a number of years and is protective of public health.

Estimate of Economic Impacts:

A standard of 30 µg/L will be required on December 3, 2003, if FDA fails to promulgate a standard, along with EPA's monitoring requirements. EPA's monitoring requirements are not appropriate for bottled water and FDA should maintain the current annual monitoring and compliance determination provisions.

The additional benefit of an FDA standard for uranium is that it protects public health. The FDA annual monitoring system for radionuclides has worked well for a number of years and is protective of the public health.

IBWA Recommendations for Regulatory Improvement

Name of Regulation: Standard of Chemical Quality – Nine Compounds Monitoring Requirement

Regulating Agency: The U.S. Food and Drug Administration

Citation: 21 CFR 165.110(b)

Authority: 21 USC 321; 21 USC 349; 21 USC 342 and 343

Description of the Problem:

The U.S. Food and Drug Administration (FDA) published a notice on August 6, 1998 announcing that the monitoring guidance requirements under the U.S. Environmental Protection Agency's (EPA) National Primary Drinking Water Regulations (NPDWR) for antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8-TCDD (dioxin) will apply to bottled water, effective February 2, 1999. The FDA has established a standard of chemical quality for bottled water on each of these compounds.

The NPDWR monitoring requirements for the four synthetic organic chemical (SOC) portion (diquat, endothall, glyphosate, and dioxin) of the nine compounds are based on a three-year cycle. During each three-year cycle, the four compounds listed above must be monitored for four consecutive quarters in one of the three years, and annually for the other two years during the cycle. Because of the application of the NPDWR monitoring requirements to bottled water, the industry has had to perform a total of six analyses for each bottled water product for the last three years. These tests have resulted in no detection for any of these four SOC compounds during this period.

This year marks the beginning of another three-year monitoring period for the four SOCs. The experience of the last cycle indicates there is not a health-based need for continuing the quarterly SOC monitoring requirement for bottled water. The intrusion of these four compounds into the water sources for bottled water, either groundwater or municipal water systems, has not been detected. The data from the prior tests completed by IBWA's members indicate that these water sources are free of these compounds.

The EPA standard provides for reduced monitoring (annual) when it is proven that the compounds are not found in a specific public water system. Since the implementation of the monitoring requirements in 1999, the bottled water industry

has not detected any of the nine compounds in question. Therefore, based on (1) the absence of detection of the compounds in bottled water, and (2) the precedent set by the EPA for the potential for reduced monitoring, the IBWA recommends that FDA clarify that these four specific compounds must be tested annually, like all other compounds tested for regulatory purposes.

Proposed Solution:

IBWA recommends that FDA 1) revise its August 6, 1998 ruling on monitoring frequencies for the four compounds listed above to conform with its good manufacturing practice regulations for all other compounds monitored annually in bottled water, and 2) issue specific bottled water guidance for the nine compounds rule that will incorporate the monitoring tests into the current annual tests required for all other compounds.

Estimate of Economic Impacts:

The current monitoring requirements for these four compounds require bottled water producers to perform six sets of tests for each bottled water product over a three period – two annual tests and one year of four consecutive quarters of testing. IBWA estimates the costs of these tests at $2,227,350 for IBWA members or about $4,650/ bottler member. The suggested change to annualized monitoring tests will reduce the number of required tests over a three period to three, thus reducing the overall costs to IBWA bottler members by approximately $1,113,000 or $2,325/ bottler member.

In addition, those states that have followed FDA's requirements would see a reduction in paperwork from the suggested change. Bottlers in many states are required to send the state agency the test results, which have shown "no detection" for the nine compounds.

There will be no adverse public health impact because the results of the current testing requirements have shown the four SOC compounds are not present in bottled water.

IBWA Recommendations for Regulatory Improvement

Name of Regulation: Standard of Microbiological Quality – Total Coliform

Regulating Agency: The U.S. Food and Drug Administration

Citation: 21 CFR 165.110(b)

Authority: 21 USC 342; 21 USC 343; 21 USC 321

Description of the Problem:

The U.S. Food and Drug Administration (FDA) issued a proposed total coliform rule for bottled water in 1993. As proposed, the rule did not focus on the central issue, i.e., presence of pathogenic organisms as indicated by the presence of *Escherichia coli (E. coli*). FDA never completed the 1993 rulemaking. Consequently, today, there is not a total coliform standard for bottled water even though total coliform standards have been set for public water supplies and by other world standard setting organizations.

Although FDA's 1993 proposed rule would have prohibited the presence of any coliform bacteria in water, it did not recognize that coliform testing often produces positive test results that indicate the presence of pathogenic AND non-pathogenic coliform and other organisms. Therefore, it is important that a confirmation test for pathogenic or harmful coliform be performed.

The presence of pathogenic organisms clearly must not be permitted in bottled water. However, before water is judged substandard, a sample that tests positive for presence of coliform organisms should be confirmed to determine the presence or absence of *E. coli,* an internationally-accepted indicator of fecal contamination and potential human pathogens. This would further reduce the risks that would otherwise undermine product integrity and consumer confidence.

A requirement for confirmatory testing is also in line with the U.S. Environmental Protection Agency's (EPA) Total Coliform Rule for public water systems and the World Health Organization's (WHO) drinking water guidelines. It has also been incorporated by the Codex Alimentarius Commission into the Codex Committee on Food Hygiene's (CCFH) Draft Code of Hygiene for Bottled/Packaged Waters (Other Than Natural Mineral Water). FDA representatives were members of the U.S. Delegation to CCFH in 1999 when the standard was considered, and supported the adoption of the standard by Codex. Regulating *E. coli* is also in line with FDA microbiological regulations for other food products.

Recognizing the need for a microbiological standard for bottled water, the International Bottled Water Association (IBWA) Board of Directors adopted a Total Coliform/*E. coli* Standard of Quality (SOQ), found in Appendix C of the IBWA Model Code, in November, 1999 (attached). This standard must be met by all IBWA members and the records subject to unannounced independent third party inspection. The IBWA Model Code SOQ states that "No *Escherichia coli* detectable in a 100 ml portion/sample. No validated total coliform is detectable in a 100 ml portion/sample as substantiated by retesting." A policy for evaluating results and determining the disposition of product is included with implementation of the new microbiological SOQ.

Proposed Solution:

IBWA recommends that FDA adopt the same standard it supported as an international standard for the Codex Alimentarius Commission: No *Escherichia coli* be detectable in a 100 ml portion/sample, and no validated total coliform be detectable in a 100 ml portion/sample as substantiated by retesting.

Estimate of Economic Impacts:

The public health will benefit by the adoption of a standard on total coliform. As indicated earlier, the detection of *E. Coli.* is an indicator of the potential presence of harmful pathogens. Although pathogens are rarely present in groundwater, the establishment of a FDA coliform standard for microbiological quality will help ensure the absence of pathogens in bottled water.

The EPA has established standards through the National Primary Drinking Water Regulation (NPDWR) for coliform in community water systems and non-transient, non-community water systems. In some states, bottled water is currently required to monitor and test for total coliform under the NPDWR. The establishment of a FDA standard will ensure consistency throughout the country in approach to total coliform that is more applicable to bottled water and ensures the safety of bottled water to protect public health.

Appendix C

Escherichia coli (*E. coli*) and Total Coliform Standard and Policy

IBWA STANDARD OF PRODUCT QUALITY

- No *Escherichia coli* detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by retesting.

PROCEDURE FOR RESPONSE TO COLIFORM AND *ESCHERICHIA COLI* TESTING RESULTS

A representative unit of production for each package size shall be tested for total coliform (which includes *E. coli* in this group) during each daily production. If positive for total coliform, an *E. coli* determination is performed from that test. When a unit of production results in a positive result for coliform organisms by a total coliform method in *Standard Methods for the Examination of Water and Wastewater,* 20th Edition, the following policy and procedure should be employed:

1. Immediately analyze 410 additional samples from the same production lot for total coliform. Also examine the original sample for presence of *Escherichia coli* (*E. coli*) by a method in Standard Methods, 20th Edition.
2. Review sampling and analytical procedures to determine if the original sample contamination may have occurred due to sampling or laboratory error. If the review of sampling and analytical procedures demonstrates a source of contamination, such as contaminated media or analyst error, INVALIDATE results and proceed with total coliform analysis of five additional samples from the same lot using uncontaminated media and proper technique.
3. Company plant personnel should use the following guidelines for decisions on the disposition of the lot:

    a. If the re-sampling does not show *E. coli* or total coliform, consider the first sample an invalid result.

    b. If the original sample AND any of the additional four samples collected are positive for total coliforms or *E. coli,* consider the results valid and conduct follow up actions pursuant to the company's recall plan.