

3177



RECEIVED
IRRC
2018 JUN 26 A 8:29

1700 Diagonal Road, Ste. 650
Alexandria, VA 22314
Ph: 703-647-4611
Fax 703-683-4074
Web: www.bottledwater.org

June 26, 2018
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Re: Final Regulation: 25 Pa. Code, Chapter 109, Safe Drinking Water, General Update and Fees, Final-Form Rulemaking Regulation #7-521 (IRRC #3177) (May 11, 2018)

Dear Commissioners:

The International Bottled Water Association (IBWA) appreciates the opportunity to comment to the Independent Regulatory Review Commission (IRRC) regarding Pennsylvania Environmental Quality Board (EQB or the Board) regulation #7-521 (IRRC #3177) (25 Pa. Code, Chapter 109 – Safe Drinking Water General Update and Fees). IBWA is the trade association representing all segments of the bottled water industry, including spring, artesian, mineral, sparkling, well, groundwater and purified bottled waters. Founded in 1958, IBWA represents domestic and international bottlers, distributors, and suppliers, including small, medium, and large companies doing business in Pennsylvania.

We are submitting these comments for consideration by the IRRC in anticipation of its Public Meeting on Thursday, June 28, 2018, at which this regulation will be discussed. In September 2017, we submitted comments to the EQB regarding its proposed Safe Drinking Water Act (SDWA) amendments. We are disappointed to see that many of our recommendations were not addressed by the EQB or the Pennsylvania Department of Environmental Protection (DEP) in the final-form rule. Likewise, we are disappointed that the IRRC's comments that repeated many of the concerns we made in our own comments also were not adequately addressed by the EQB in this final-form regulation.

In the comments that follow, we explain why the IRRC should vote to disapprove this final regulation. We have concerns with four particular aspects of the regulation and regulatory process:

1. The permitting fee provisions as applied to bottled water systems warrant reconsideration and modification.
2. The requirements in § 109.503(a)(1)(A) for a "pre-drilling plan" should be clarified and adjusted to avoid duplication with similar aquifer test plan requirements administered by other agencies.
3. Clarification is needed about whether § 109.602 (regarding acceptable design) will be applied to bottled, vended, retail, and bulk water hauling (BVRB) systems.

4. Confirmation testing of source water under § 109.1303 should remain consistent with Federal standards and other states that regulate bottled water.

In each section of these comments that follows, we explain why we are concerned that the EQB failed to comply with Section 5.1(a) of the Regulatory Review Act (RRA)¹, which directs the EQB to respond to all comments received from IRRC or any other source.² We also explain why the regulation is not in the public interest under RRA criteria. Our comments first summarize the key issue addressed in IBWA's comments on the proposed rule (Original IBWA Comments). Next, we repeat the IRRC comments (IRRC Comments) on the proposed regulation (submitted Oct. 25, 2017). We then provide the relevant response from the EQB (EQB Response) addressing the IRRC Comments (as published together with the final-form regulation on May 11, 2018). Finally, IBWA explains our concerns about why the EQB did not adequately address the IRRC comments (IBWA Follow-Up Comments) and why the regulation is not in the public interest. We also reiterate previously made comments that were not specifically referenced by the IRRC in its October 25, 2017 comments. We conclude our comments by providing feedback on a few specific sections of the final-form regulation.

1. The permitting fee provisions as applied to bottled water systems warrant reconsideration and modification.

Original IBWA Comments: In its comments on the proposed rule, IBWA raised concerns about the structure and lack of fairness of the proposed permitting fees, as applied to bottled water systems.

IRRC Comments:

Public comments opposing the proposed fees, and even those supporting them, challenge the Board's methodology for assessing the fees. The commenters question whether fees based on parameters including population served, public water system identification number and system construction, bear a reasonable relationship to the actual cost of the services provided by the Department. We recommend that the Board reevaluate the basis of the fees in the final-form regulation, including consideration of the recommendation from the Technical Assistance Center for Small Drinking Water Systems (TAC).³ We ask the Board to explain in the Preamble of the final regulation how the chosen method of assessment of fees bears a reasonable relationship to the actual cost of providing each service, and to explain why the TAC recommendation is not in the public interest if it is not adopted.⁴

...

¹ 71 P.S. § 745.5a(a).

² Please note that all of the footnotes in this comment are our own, rather than part of the original sources being quoted.

³ The Board notes in the Preamble that the TAC suggested using gallons produced as the basis for determining the annual fee for community and bottled, vended, retail and bulk hauling (BVRB) water systems. In the Preamble, the Board dismisses this recommendation stating, "The Department does not currently have sufficient data to determine the gallons produced as this is not a required data held."

⁴ See pg. 4 of the IRRC Comments.

Commenters state that the Board's analysis of costs does not properly reflect the costs to their water systems and that the basis of the fees is not consistent with their current billing. We strongly encourage the Department to organize additional stakeholder meetings with representatives from all segments of the regulated community in order to develop final-form regulations that are clear, reasonable and have the least adverse economic impact while protecting the public health, safety and welfare. We ask the Board to address the reasonableness, economic impact and implementation of changes made to these sections of the final-form regulation in the revised Preamble.

Further, if significant revisions to the regulation are being considered as a result of this input, the regulated community and other interested parties should be afforded an opportunity to review and comment on the text of the regulation through publication of an Advanced Notice of Final Rulemaking (ANFR). An ANFR would provide the opportunity to review and reach consensus on remaining issues before submittal of a final-form regulation.⁵

...

We ask the Board to consider regulatory methods to minimize adverse impacts on small businesses or explain the reasonableness of not considering alternatives.⁶

EQB Response:

The Department retained the assessment of fees by population served. Nearly all aspects of the State and Federal drinking water program are governed by system size (population). System population is used to determine monitoring requirements (both the number of samples and the frequency of monitoring), implementation due dates (many rules phase-in effective dates by system size), and treatment techniques (some treatment techniques only apply to certain system sizes), among other things. System population is used as a surrogate for system complexity—medium and large systems are generally more complex than small systems, with more overall facilities (namely, sources, entry points, interconnections, and storage tanks, among others) and types of treatment technologies. Medium and large systems often face additional challenges with maintaining simultaneous compliance, which factor heavily into Department services. For these reasons, it is appropriate to use system population to determine the various fee categories and Department costs. Refer to the discussion regarding Section 109.1402 in Section E, below, for more information about the appropriateness of the fees.⁷

...

Section E 109.1406.

⁵ See pg. 6 of the IRRC Comments.
⁶ See pg. 5 of the IRRC Comments.
⁷ See pgs. 173 – 174 of the Board Response.

Subsections (a) and (b) were amended to change the number of people in the populations served for the smallest category of public water systems (PWSs) in the same manner as discussed in the changes to Section E 109.1404.⁸

Section E 109.1404.

The preamble to the proposed rule included an extensive explanation regarding the appropriateness of the fees, and how the fees bear a reasonable relationship to the actual cost of services provided. Please see the preamble to the proposed rulemaking at 47 Pa.B. 5005—5010 for the full explanation.⁹

Additionally, the Board provided the same analysis as provided in the proposed rule for estimated cost, explaining that cost of services depends on the specific circumstances and will vary widely. The Board provided the same table summarizing the Department's costs of providing services that can be estimated for community water systems (CWSs) serving various populations. These activities include conducting sanitary surveys, conducting other inspections, determining compliance, maintaining PADWIS/eFACTS, reviewing plans/reports, and providing technical assistance/training.¹⁰ Examples provided of other services and costs that involve variable circumstances and preclude a single estimate for the services include sanitary surveys that take longer to conduct to the complexity or size of the water system; additional follow-up in response to a violation; additional follow-up, corrective and emergency actions taken in response to a water emergency (based on emergencies that occurred in 2011, 2012, 2015, and 2016); cost of samples taken during inspections and filter plant performance evaluations, in response to complaint investigations, and to assess water quality and protect public health during water supply emergencies; costs associated with additional training when new regulations are promulgated; and costs associated with specific follow-up actions established in new regulations.¹¹

As discussed in the preamble to the proposed rule, the Department considered alternatives to assessing fees. However, the other options would have resulted in further disparity between the fees and Department costs for services for the very small and very large water systems. The Department retained the fee structure based on population served because it was the best option to comply with the statutory language in the SDWA that directs the Board to establish fees for services that bear a reasonable relationship to the actual costs of the services provided. 35 P.S. § 721.4(c). The Board emphasizes that the SDWA requires that the fees assessed by the Department "bear a reasonable relationship" to the actual costs of the services provided, not that the fees be the "exact" costs for the services provided.¹²

⁸ See pg. 193 of the Board Response. The number of people in the populations served for the smallest category of public water systems was changed to 100 or less.

⁹ See pg. 188 of the Board Response.

¹⁰ See pgs. 189, 220 of the Board Response

¹¹ See pgs. 189 – 191, 220-222 of the Board Response; see also § 109.1406, 47 Pa.B. 4986 (Aug. 26, 2017) <https://www.pabulletin.com/secure/data/vol47/47-34/1413a.html>.

¹² See pg. 192 of the Board Response.

Regarding the other annual fees in subsection (a), annual fees for bottled water systems are \$2,500; and annual fees for vended, retail and bulk water systems are \$1,000. These fees were determined using the same criteria as discussed above.¹³

...

The fees and other proposed amendments were thoroughly discussed with TAC and other stakeholders through several advisory committee meetings and a public webinar. Advisory committee meetings were announced publicly and are open to the public. As mentioned above, several general update provisions were either modified or deleted in response to TAC and public comments. In addition, several options were evaluated using all available data to determine the best method of assessing fees to ensure the fees bear a reasonable relationship to the actual cost of services provided by the Department and in a manner that minimizes the adverse impact on water systems with fewer customers to bear the cost.¹⁴

The Department does not currently have complete data on gallons produced. Moving forward, the Department will consider revisions to reporting forms so that this data may be available in the future. However, even if this data were available, the Department believes that establishing fees based solely on gallons produced would present additional challenges. Not all water systems are metered or have meters installed in the correct locations to track gallons produced. Some water systems produce and sell raw water for non-potable purposes, such as in the oil and gas industry, and it is unclear whether those volumes would be included. Other water systems have high levels of unaccounted for water due to unmetered connections, fire protection, and waterline leaks and breaks. Finally, gallons produced may not be commensurate with the complexity of water system facilities and types of treatment provided. For these reasons, the use of gallons produced to assess fees would not bear a reasonable relationship to the cost of services provided by the Department.¹⁵

The Board must also consider the impacts of the proposed fees on small businesses as part of the regulatory analysis required under the RRA. The Department considered several alternatives for assessing fees. In the end, the proposed fees were retained in the final-form rulemaking because the Department believes the fees will provide the funding necessary to properly administer the SDWA and provide the wide variety of necessary services in a manner that minimizes the adverse impact on water systems with fewer customers to bear the cost.¹⁶

IBWA Follow-Up Comments: As explained above, the IRRRC requested that the Board explain in the Preamble of the final-form regulation how the chosen method of assessment of fees bears a reasonable relationship to the actual cost of providing each service, and to explain why the TAC recommendation is not in the public interest if it is not adopted. The Board responded by stating the proposed rule included an extensive explanation regarding the appropriateness of the fees, and how

¹³ See pgs. 192-193 of the Board Response.

¹⁴ See pgs. 175, 242-243 of the Board Response.

¹⁵ See pg. 225 of the Board Response.

¹⁶ See pg. 217 of the Board Response.

the fees bear a reasonable relationship to the actual cost of services provided. Additionally, the Board provided the same table of estimated costs for CWSs serving various populations, as well as descriptions of examples that do not allow for specific estimates.

However, IBWA maintains that the following IRRC Comments and IBWA Comments were not sufficiently addressed:

- The Board response did not address the definition of "populations served." First, "population served" is not a concept utilized in relation to classification of bottled water operations, and it is far from clear what it means here. Bottled water manufacturers do not have a way to count or ascertain the number of different individuals who drink their product each day or over a year. A small company that produces just 1,000 bottled water cases of 24 16.9-ounce bottles each per day (24,000 bottles per day = ~3,169 gallons per day (gpd)) might be viewed as serving a population over a year of 365,000, if you assume that each case is purchased by a different person, or it could be seen as serving a population of 8,760,000 if you assume each bottle produced in a year is consumed by a separate person. The point is that the calculation of population served by a bottled water system is impossible, and rather meaningless, and bears no relation to the size or complexity of the operation in terms of drinking water permit review and inspection time. The calculation then renders the EQB estimated costs (whether single or variable) meaningless, as the hours required to complete the activities are based on numbers that are not ascertainable for bottled water manufacturers.
- The inability to calculate the actual population served then renders the fee schedule based on estimated and variable costs inapplicable, and does not accurately capture the time or cost involved in permit review and inspection for bottled water operations, particularly when compared to community water systems. Using the example above, under the Department's final-form regulation, the permitting fee under § 109.1406 for such a very small bottled water producer (3,169 gpd) could equal that imposed under § 109.1404 for the very largest community water systems (with populations of over 100,000), such as Allentown and Philadelphia. To put this in perspective, a community system serving population of 100,000+ population would be expected to have a daily production of 10 million gpd (based on consumption of 100 gallons per capita per day) – or about 3,155 times the amount produced daily by the small bottled water producer.¹⁷ That seems hard to justify, given that almost all bottled water operations utilize groundwater sources, with relatively straightforward filtration and disinfection systems and no issues related to distribution systems, compared to community and non-community systems which often use surface water or groundwater under the influence of surface water sources, and have extensive distribution systems requiring testing at not only the point of entry but at distant points of delivery.
- The time and effort of regulating bottled water systems is not related to production volume (bottles produced or number of customers), but rather the nature of the operation. The permitting application for a bottled water producer would be based on an evaluation of a production line that involves storage, filtration, disinfection and bottling, not on the number of bottles produced. We expect the time needed to review a permit for a bottled water company

¹⁷ From another perspective, a piped water system that only distributes 2400 gpd would be on the cusp of not even qualifying as a public water system, as that amount would support < 100 individuals at a per capita use of 100 gpd.

would be considerably less than the time needed to review a traditional municipal water system, and so any fees should be proportionately lower.

- The EQB's response does not sufficiently address the concerns that the same fee is imposed for an entirely new construction permit or for any "major construction permit amendment." The concept of "major amendment" under § 109.1005(f)(1)(i) includes new sources,¹⁸ additions or deletions of treatment techniques or processes and new types of products. Some of the amendments swept into these high fees should not take a substantial amount of time to review, e.g., additional ultraviolet light.
- The EQB's response does not adequately address concerns regarding small businesses, where paying even a small fee can constitute a genuine financial hardship. It is not uncommon for governmental user fee programs to provide small businesses with a significantly reduced rate (e.g., 25% or 50% of the standard fee). We urge DEP to employ this same principle to any fees imposed on bottled water companies.^{19,20}
- The Board did not organize stakeholder meetings after the IRRC Comments issued to allow for all segments of the regulated community to develop final-form regulations that are clear, reasonable, and have the least adverse economic impact while protecting public health, safety and welfare. This is directly contrary to the IRRC's strong recommendation.

2. The requirements in § 109.503(a)(1)(A) for a "pre-drilling plan" should be clarified and adjusted to avoid duplication with similar aquifer test plan requirements administered by other agencies.

Original IBWA Comments: The EQB proposed to amend § 109.503(a)(1) (construction permit requirements) to add a new step in the process – requiring submission and DEP approval of a "pre-drilling plan" for any new groundwater source "prior to the well construction and conducting an aquifer test." As part of this "pre-drilling plan," the proposed rule would require submission of the preliminary results of a source water assessment, a hydrogeologic description, an aquifer test monitoring plan, and a proposed well construction design. IBWA explained why this proposal should be reconsidered and that the current arrangement for informal review is working.

¹⁸ We note that a Board response indicates "Subsection 109.503(b)(2) was amended in this final-form rulemaking to clarify that a change to a source designation *may be* considered a minor amendment." See pg. 181 of the Board Response (emphasis added).

¹⁹ Note, Regulatory Analysis Question #24 addresses adverse impacts on small business for source water protection and new source permitting requirements, as well as surface water and GUDI filter plants, but does not address non community water systems. See pgs. 43-45 of the Board Response.

²⁰ Additionally, Regulatory Analysis Question #27 states, "the impact of this rulemaking — the provision of safe drinking water to this Commonwealth's populace — is unrelated to whether the regulation is implemented by small or large businesses. Ultimately, regulatory compliance puts all of the regulated community in the best position to prove that water they provide is safe to drink, thereby providing necessary protection of public health." See pgs. 47-48 of the Board Response.

IRRC Comments:

We ask the Board to clarify the pre-drilling plan and source water assessment requirements of 109.503(a)(1) in the final regulation. Related to the pre-drilling plan, IBWA asked “why it is necessary to establish a new approval requirement under which all public water systems must stop and wait for agency staff to review aquifer test plans before proceeding with the tests required for a full construction permit application.” Considering the Department’s stated difficulty in addressing the minimum requirements for SDWA primacy noted in the Preamble, we ask the Board to explain the reasonableness of this requirement.²¹

EQB Response:

Predrilling plans and source approvals are coordinated with other agencies such as the Susquehanna River Basin Commission (SRBC), Delaware River Basin Commission (DRBC), etc. The individual components of a pre-drilling plan and subsequent approvals of potential production well site locations have been required as part of the permitting process since at least 1997. The individual components are currently listed in § 109.503(a)(1)(iii) (relating to PWS construction permits) of the existing regulations and are required to be submitted to the Department as part of a construction permit application. However, with these revisions, the predrilling plan will now be required to be submitted to the Department for review and approval prior to drilling the well. No change to this subsection has been made in the final-form rulemaking.

Test wells and exploratory activities would be undertaken first to determine potential production well site locations; the Department does encourage these valuable data gathering activities. Potential production well sites would then be addressed by the pre-drilling plan.

The clarifications to existing requirements for preliminary source water assessments in § 109.503(a)(1)(iii)(A) do not involve water quality monitoring and are primarily to determine potential sources of contamination and the susceptibility of the production water source to contamination, not to assess existing water quality in the well. In addition, the Groundwater Monitoring Guidance Manual is used by DEP and multiple agencies to address groundwater sampling/monitoring issues. Refer to Section F of this preamble, Benefits, Costs and Compliance, under the Benefits heading, for more information.²²

IBWA Follow-Up Comments: IBWA maintains that the following comments provided by IBWA and IRRC were not sufficiently addressed in relation to bottled water operations:

- The Board’s response does not clarify the contents of the pre-drilling plan. Many bottled water operators and other public systems operators will conduct preliminary hydrogeologic studies and tests to evaluate potential sources before conducting more formal “aquifer tests.” Such hydrogeologic studies often involve drilling a series of test wells and conducting

²¹ See pgs. 7-8 of the IRRC Comments.

²² See pgs. 176, 228 of the Board Response

preliminary short duration pumping to evaluate specific capacity and take water quality samples in order to ascertain whether the site is likely a suitable source. In this regard, the final-form regulation language in § 109.503(a)(1)(iii)(B) is confusing. It refers to a “pre-drilling plan,” which suggests by its terms that something must be submitted to and approved by the Department before any well is drilled. But then it also calls for submitting with the plan the preliminary results of source water assessments, a key part of which involves water quality samples – and such source samples cannot be taken without some type of test well. The Board’s response that “test wells and exploratory activities would be undertaken first to determine potential production site locations” is contradictory to first submitting a pre-drilling plan for new groundwater sources.

- As highlighted throughout the preamble to the proposed rulemaking and in the Board’s response document, the Department’s drinking water staff is already stretched very thin, finding it difficult to address the minimum requirements for the SDWA primarily in terms of inspections and permit oversight to assure drinking water quality. In that context, a question must be raised as to whether and why it is necessary to establish a new approval requirement under which all public water systems must stop and wait for agency staff to review aquifer test plans before proceeding with the tests required for a full construction permit application. The Department has provided guidance concerning aquifer testing protocols that allows system operators and their hydrogeologic consultants to design appropriate test plans. The Department currently reviews such plans on an informal basis, and often provides comments. By mandating formal agency approval before proceeding (basically, making this another permit requirement), this rule could create a new bottleneck in the process of obtaining required sources of water to meet water system quantity and quality demands.
- Aquifer test plans are currently reviewed by other agencies, sometimes in much greater detail than the Department can accord. For example, over two-thirds of the Commonwealth, the Susquehanna River Basin Commission already requires submission of aquifer test plans for groundwater withdrawals involving 100,000 gallons per day or greater from one or a combination of wells. There should be no need to duplicate those other agencies’ aquifer plan review efforts.

Considering the above points, we would suggest that the Department reconsider the concept of mandating “approval” of an aquifer test plan before proceeding with a test. The current arrangement for informal review works well, does not put an extra unnecessary burden on the Department’s resources, does not unduly increase the cost and timeline of permitting. .

At the very least, we would recommend that § 10.503(a)(1)(iii)(B) be modified to make clear that this is not a “pre-drilling plan” but rather a plan that would precede conduct of a formal aquifer test.

Finally, we continue to seek clarification on whether the turbidity limits cited will apply only to surface water or Groundwater Under the Direct Influence (GUDI) sources, or if they will also apply to non-GUDI groundwater sources.

3. Clarification is needed about whether § 109.602 (regarding acceptable design) will be applied to BVRB systems.

Original IBWA Comments: IBWA commented that the requirement in § 109.602 for alarms and shutdown capabilities is generally more suited for community water systems and needs to be clarified for how it would apply to a BVRB system.

IRCC Comments:

We ask the Board to ensure that the final-form Regulatory Analysis Form (RAF) and regulation make clear who is required to comply with the regulation and how the final-form regulation affects the various segments of the regulated community.²³

EQB Response:

The various definitions and types of PWSs that must comply with the SDWA and regulations are not being amended by this final-form rulemaking. The existing State and Federal regulatory definitions and guidance provide more information about the types of water systems. In general, nontransient noncommunity water systems include facilities that serve 25 or more of the same people, but are not residential facilities. This includes schools and places of business with 25 or more employees. Transient noncommunity water systems generally serve a transient population and include restaurants and campgrounds. Finally, the fees for small water systems and businesses were established to bear a reasonable relationship to the actual cost of services provided and in a manner that minimizes the adverse impact on water systems with fewer customers to bear the cost. Refer to Section F of this preamble and to the responses to Questions 17, 24, 26 and 27 in the RAF for this final-form rulemaking for more information about who is required to comply with the regulation, how the final-form regulation affects the various segments of the regulated community, the costs for the various segments of the regulated community, including small businesses, and for the consideration of alternative regulatory approaches.²⁴

...

*Automatic Alarms and Shutdown Capabilities:*²⁵ Filter plants are complex and dynamic. In response to many circumstances, the water plant operator must take an immediate action to protect public health, such as when source water quality changes, chemical feed pumps malfunction, filters require backwashing, or other unforeseen circumstances occur. Water plant operators are often required to perform other duties, which leave water plants unattended, and which limit operators' ability to respond immediately to treatment needs.

Automated alarms and shutdown capabilities play an important role in modern water treatment and public health protection. Many water suppliers have already taken advantage of readily available technology to reduce personnel costs while still providing safe water to their customers. The amendments will ensure that all surface water filtration plants have the minimum controls in place to ensure that operators are immediately alerted to major treatment problems. The amendments will also ensure that

²³ See pg. 5 of the IRRC Comments.

²⁴ See pg. 174-175 of the Board Response.

²⁵ See pg. 196 of the Board Response.

unmanned filter plants are automatically shut down when the plant is producing water that is not safe to drink, which prevents contaminated water from being provided to customers for extended periods of time. These alarm and shutdown capabilities will allow operators at both attended and unattended filtration plants to promptly respond to the water quality problems and treatment needs of the plant. The automated plant shut down is intended to prevent poor quality water from reaching customers, which will protect public health, reduce PWS costs related to corrective actions and issuing public notice, reduce costs to the community, and maintain consumer confidence.

The proposed alarm and shutdown capability amendments under § 109.602 (relating to acceptable design) remain in this final-form rulemaking, which are also targeted at surface water filtration plants. The automated plant shut down requirements are intended to prevent poor quality water from reaching customers, which will protect public health, reduce PWS costs related to corrective actions and issuing public notice, reduce costs to the community, and maintain consumer confidence. Therefore, the improved alarm and shutdown capabilities that will occur as a result of systems complying with this final-form rulemaking are a very important interim public health protection measure which will be in place while the Department awaits EPA's final actions on potentially more stringent turbidity provisions.²⁶

IBWA Follow-Up Comments: While the Board's response states that the alarm and shutdown capability amendments are targeted at surface water filtration plants, the Board's responses do not clarify how the requirements for alarms and shutdown capabilities apply to a BVRB facility. The Board response appears to be written for a CWS with surface water or GUDI sources, but there is not a specific exclusion for noncommunity water systems/BVRB systems.

4. Confirmation testing of source water under § 109.1303 should remain consistent with Federal standards and other states that regulate bottled water.

Original IBWA Comments: The final-form regulation should retain the current provision in § 109.1303 that allows for 5 successive *E. coli* tests prior to triggering corrective actions and public notification. The EQB should also take this occasion to clarify in the regulations that no public notification should be required where the water system has in place an adequate treatment program.

IRRC Comments:

IBWA opposes the Board's proposed deletion of the existing opportunity to collect five additional source water samples from the same source within 24 hours of being notified of the *E. coli*-positive sample to confirm if there is a problem. They state that this is an essential step to address the legitimate potential for false positives for this testing, and has been a long-standing practice in Pennsylvania based on regulations promulgated by the Environmental Protection Agency (EPA). If the deletion is maintained in the final-form regulation, we ask the Board to address the reasonableness and economic impacts of eliminating the opportunity for further testing to prevent false positives.²⁷

²⁶ See pgs. 5, 178, 233 of the Board Response.

²⁷ See pg. 8 of the IRRC Comments

EQB Response:

EPA approves analytical methods based on the reliability of a method to have a low risk of samples being false positive or false negative. In the preamble to the proposed Federal Ground Water Rule, EPA states, "that, in the interest of public health, a positive sample by any of the methods listed in Table III-4 should be regarded as a fecal indicator-positive source water sample." 65 FR 30230 (May 10, 2000). The proposed and final Federal rules along with the Department's revisions to Chapter 109 provide a means for the laboratory or state to invalidate samples. Although EPA allowed the five additional *E. coli* samples as a concession relating to the rare event that a sample is false positive, EPA's commentary in the preamble to this final rule states "that in most cases these five additional samples should capture the fecal contamination event since the samples are taken within 24 hours." 71 FR 65594 (November 8, 2006). This statement acknowledges that a risk to public health exists because the five additional samples may miss detecting the fecal contamination. In other words, the fecal contamination that was detected in the original sample was a true positive; however, because contamination is neither constant nor immobile, the five additional samples may miss detecting the contamination event. This risk of missing the event is the main rationale for the Department's decision to delete the five additional samples.

Further supporting this position, the Federal regulations at 40 CFR 141.402(g) along with Chapter 109 acknowledge the risk to public health from a single *E. coli* positive sample by requiring Tier I public notification (PN) for any source water sample testing positive for *E. coli*. This Tier I PN is required to be issued within 24 hours of notification of the initial sample testing positive. Under the Federal rules, if five additional *E. coli* samples are allowed by a state, the Tier 1 PN must still be issued upon notification of the first positive sample and not be postponed while waiting for the results of additional samples. The deletion in the final-form rulemaking of the option for five additional samples makes Chapter 109 more consistent with the Food and Drug Administration's (FDA) regulations which bottled water systems are also required to follow. The FDA regulations at 21 CFR 129.35(a)(3)(i) provide in relevant part that "[b]efore a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its reoccurrence. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative. Records of approval of the source water by government agencies having jurisdiction, records of sampling and analyses for which the plant is responsible, and records describing corrective measures taken in response to a finding of *E. coli* are to be maintained on file at the plant." The FDA regulations recognize the five additional samples as a means to show that a corrective action taken in response to a single positive sample has eliminated or established protection of the source from fecal contamination.

Concerning "adequate treatment" as it relates to 4-log inactivation and/or removal of viruses, the Federal rule at 40 CFR 141.403(b) only allows a system to be relieved of the requirement to conduct triggered source water monitoring if the system notifies the state in writing that it provides at least 4- log treatment of viruses and begins compliance monitoring in accordance with paragraph (b)(3). Notification to the State must include

engineering, operational, or other information that the State requests to evaluate the submission, which in Pennsylvania is accomplished through the permitting process. The Federal rule does not allow systems, which have not provided notification and information to the State and are not conducting the required compliance monitoring, to retroactively demonstrate 4-log treatment had been provided in order to avoid public notification.

Regarding economic impact, water systems will no longer be required to collect the five additional *E. coli* samples, which will result in a potential cost savings. Further, all bottled water systems are already required to provide continuous disinfection. So, if 4-log treatment is triggered, no additional capital costs will be incurred—treatment already exists. However, some bottled water systems will need to modify operational practices using existing treatment, and improve associated monitoring and reporting practices, as specified in revised operations permits, to insure adequate 4-log treatment is maintained.²⁸

IBWA Follow-Up Comments: We are concerned that the EQB only superficially addressed our concerns. When you consider their response in more depth, it becomes apparent that this aspect of the proposal lacks justification. We offer the following points in this respect:

- The EQB fails to provide an adequate explanation for eliminating the opportunity to conduct confirmation testing. The EQB explains:

Although EPA allowed the five additional *E. coli* samples as a concession relating to the rare event that a sample is false positive, EPA's commentary in the preamble to this final rule states 'that in most cases these five additional samples should capture the fecal contamination event since the samples are taken within 24 hours.' 71 FR 65594 (November 8, 2006). This statement acknowledges that a risk to public health exists because the five additional samples may miss detecting the fecal contamination. In other words, the fecal contamination that was detected in the original sample was a true positive; however, because contamination is neither constant nor immobile, the five additional samples may miss detecting the contamination event. This risk of missing the event is the main rationale for the Department's decision to delete the five additional samples.

EPA's statement quoted above supports our position that if there is fecal contamination in the source water, the follow up sampling is appropriate so long as it is performed within 24 hours. This statement is acknowledging that follow-up sampling works, contrary to the EQB's erroneous conclusion that EPA is acknowledging flaws with the five follow up sample approach. In fact, FDA goes on to state in the same paragraph quoted above: "Thus, if an initial fecal indicator-positive is detected at the well, that occurrence should be detectable again with additional samples within 24 hours."²⁹ Thus, the EQB has failed to meet the IRRC's direction to address the reasonableness of eliminating the opportunity for further testing to prevent false positives.

- Regarding economic impact, the EQB's justification is not grounded in fact. The EQB explains that not collecting five additional *E. coli* samples will "result in potential cost savings." This is not correct, as the multi-million dollar cost of an unnecessary recall of

²⁸ See pgs. 240-241, 177 of the Board Comments.

²⁹ 71 Fed. Reg. 65574, 65594 (Nov. 8, 2006).

bottled water due to a false-positive in the source water far exceeds the nominal cost for testing five more samples. There is a real potential for false-positives. As acknowledged by the EPA, “the false-positive rate for *E. coli* is 7.2% for the E*Colite Test, 2.5% for the ColiBlue24 Test, and 4.3% for the membrane filter test using MI Agar.”³⁰

Moreover, although contaminated source water will receive a disinfection treatment, DEP has a history of not acknowledging all forms of treatment as adequate to justify not performing a recall based on a positive *E. coli* test in source water. The EQB acknowledges that there are additional costs required to bring a treatment system in line with DEP’s expectations, including capital costs, but fails to consider these costs when it summarily concludes that eliminating the requirement to collect five follow-up samples will result in cost savings. The EQB’s logic here is flawed and does not adequately address the reasonableness of the economic impacts of this rule.

- We also disagree with the EQB’s discussion of the bottled water Ground Water Rule in its Comment and Response Document.³¹ That document refers to the U.S. Food and Drug Administration’s (FDA’s) bottled water regulation in 21 C.F.R. § 129.35(a)(i), which provides that before a bottler can use source water from a source that tested positive for *E. coli*, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination in the source in a manner sufficient to prevent its recurrence. The rule requires that following a contamination event and remediation, five samples must be collected over a 24-hour period from the same sampling site and found negative for *E. coli*. The EQB explains that “the deletion in the final-form rulemaking of the option for five additional samples makes Chapter 109 more consistent with the FDA’s regulations which bottled water systems are also required to follow.” This is a non sequitur. FDA’s regulation is about remediating a source and acknowledges that multiple samples are required to confirm that the source is clear. In contrast, the regulation at issue in this rulemaking is implemented for consistency with U.S. Environmental Protection Agency (EPA) regulations and the EQB is proposing to not allow for multiple samples to confirm that the source has a problem. Comparing FDA and EPA rules on this issue is like comparing apples to oranges.

In summary, we are concerned that the EQB did not adequately consider our comments or address the IRRC’s recommendations.

5. The following comments are provided on specific sections of the proposed rule.

a. § 109.1

IBWA Follow-Up Comments: We continue to request clarification on how bottled water manufacturers and bulk water sources are classified.

b. § 109.602 (see also our comments under Item #3 above)

IBWA Follow-Up Comments: We continue to request clarification on if the revised public water system design standards apply to bottled water facilities.

³⁰ 65 Fed. Reg. 30194, 30230 (May 10, 2000).

³¹ See pg. 31 of the Comment and Response Document.

c. § 109.701 (referred to in §109.1008)

IBWA Follow-Up Comments: With regard to increased reporting and recordkeeping requirements for turbidity, required reporting of THM and disinfection byproducts, and special reporting for filters that exhibit turbidity above designated levels, we are wondering whether the 1 hour reporting requirement applies to bottled water facilities.

d. § 109.1402(a)(4) (see also our comments under Item #1 above)

IBWA Follow-Up Comments: The proposed annual fee for bottled water systems is \$2,500 per year. The fee due date under § 109.1401(c)(4) depends on "population served" by the system. The proposed rule contains no explanation as to how the population served by a bottled water system is to be determined.

In conclusion, we urge the IRRC disapprove this final regulation. The EQB failed to comply with the RRA in this rulemaking and the regulation is not in the public interest under RRA criteria.

Thank you for your consideration of our comments. If you have any questions, please do not hesitate to contact us.

Respectfully submitted,



INTERNATIONAL BOTTLED WATER ASSOCIATION

Robert R. Hirst
Vice President – Education, Science, and Technical Relations

Ph: (703) 647-4611

EM: bhirst@bottledwater.org