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Kathy Cooper

From:	Tiffany M. Moseley <tmoseley@niagarawater.com>
Sent:	Monday, October 16, 2017 7:28 PM
To:	IRRC
Cc:	Michelle Elliott; James Smith; Fiona Wilmarth; RegComments@pa.gov
Subject:	Niagara Bottling Comments to IRRC on the PA Safe Drinking Water Proposed Rule
Attachments:	Niagara Comments to IRRC on PA Safe Drinking Water Proposed Rule.pdf; Niagara Comments on Pennsylvania Safe Drinking Water Proposed Rule - 9-2....pdf

Dear Commissioners,

On behalf of Niagara Bottling, LLC, I am writing to encourage the IRRC to submit comments opposing several aspects of the Environmental Quality Board's (Board) proposed rulemaking addressing the State's safe drinking water regulations in 25 Pa. Code Chapter 109. The attached letter first summarizes the comments we submitted to the Board regarding this proposal (see attached) and then addresses why the Board's proposal is not in the public interest, as evaluated under the criteria in the Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). We appreciate your time and consideration in reviewing this material.

Tiffany Moseley I Director of Compliance & Regulatory Affairs I **Niagara Bottling** I 2560 E. Philadelphia St I Ontario,CA 91761 USA I Mobile 909.270.0624 I Fax 909.354.3642 I tmoseley@niagarawater.com

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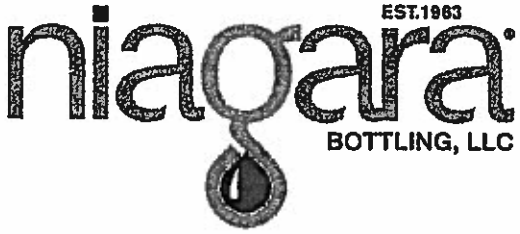

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IRRC
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October 16, 2017

VIA EMAIL TO irrc@irrc.state.pa.us

Independent Regulatory Review Commission
333 Market St, 14th Floor
Harrisburg, PA 17101

RE: Proposed Rulemaking; 25 Pa. Code Ch. 109, Safe Drinking Water; General Update and Fees; 47 Pa. Bulletin 4986 (Aug. 26, 2017)

Dear Commissioners:

On behalf of Niagara Bottling, LLC, I am writing to encourage the Independent Regulatory Review Commission (IRRC) to submit comments opposing several aspects of the Environmental Quality Board's (Board's) proposed rulemaking addressing the State's safe drinking water regulations in 25 Pa. Code Chapter 109. Family owned and operated since 1963, Niagara Bottling is the leading private label bottled water company in the United States. Niagara has geographically diversified production facilities throughout the United States, including in Pennsylvania.

The Board has proposed concerning revisions to § 109.1303 of the Safe Drinking Water regulations regarding responding to initial positive *E. coli* findings in source water samples. The Board proposes eliminating the important requirement to conduct confirmation testing upon receiving initial positive *E. coli* test results, even though it is well established that there is a high false positive rate for these tests. Moreover, under the proposed revisions a single positive *E. coli* finding would immediately necessitate so-called "Tier 1 public notification requirements" (i.e., public notice), which for bottled water functionally results in a full-blown product recall because consumers have no option other than to dispose of any on-hand product. This notice would be mandated, even if – as exists for Niagara's Pennsylvania facilities – the water system has a treatment process in place to protect against any potential *E. coli* in the water. In other words, the proposal would force a product recall even where the bottled water is perfectly safe to drink. Because the Board's proposal is not in the public interest, we urge the IRRC to submit its own comments objecting to the proposed rule pursuant to 71 P.S. § 745.5(g).

I want to underscore that nothing is more important to us than consumer safety. Indeed, nothing in our comments to the Board, if adopted, would do anything to lessen the current level of public health protection that residents of the Commonwealth of Pennsylvania now enjoy and deserve. To the contrary, our comments are directed at preserving consumer access to safe bottled water. All we are asking is that companies be allowed to demonstrate to the state that their products are safe and that a product recall not be required based on a single, unconfirmed, initial positive

finding of *E. coli* in source water. Of course, if a company is not able to demonstrate its product is safe for consumption, all the requisite remedies should apply.

This letter first summarizes the comments we submitted to the Board regarding this proposal (attached as Appendix 1) and then addresses why the Board's proposal is not in the public interest, as evaluated under the criteria in the Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). We also explain that the IRRC should elect to review § 109.1303 of the current regulation, as allowed by Section 8.1 of the RRA (71 P.S. § 745.8a), and recommend changes to this regulation because it is contrary to the public interest when applied to a bottled water manufacturer with an effective, but non-permitted, treatment system in place. As discussed further herein, reasons that the proposal and existing regulation are not in the public interest include the following:

- The Board's proposal would be costly and waste safe bottled water by requiring that water systems conduct corrective actions and engage in public notifications after a single, unverified initial positive *E. coli* sample. This is especially so when the desired confirmation testing can be conducted quickly.

- Eliminating the provision requiring five confirmation samples does nothing to promote public health. To the contrary, the Board's proposal will result in unnecessary concern among the public in situations where the water at issue is perfectly safe, which could readily be established by further testing.

- The Board's proposal to discontinue confirmation testing for *E. coli*-positives would diverge from the U.S. Environmental Protection Agency (EPA) standard under the Ground Water Rule, Pennsylvania's existing regulation, and the approach taken in many other jurisdictions.

- There is very limited discussion in the preamble to the proposed rule regarding the Board's rationale for this significant proposed revision to §109.1303. The Board has failed to proffer an adequate justification for its proposal, contrary to foundational tenets of administrative law.

- It is not reasonable to require corrective action and Tier 1 public notification without confirming that the initial sample is indeed positive.

- The current regulation in § 109.1303 imposes unnecessary costs on industry and wastes natural resources when the system has an effective treatment process in place.

- Application of the Tier 1 public notice requirements to systems with lawful 4-log treatment (but no state permit) provides no benefit to public health.

- The Tier 1 public notification is confusing when issued by bottled water manufacturers.

- It is unreasonable for the State to require systems with an effective 4-log treatment for harmful viruses and bacteria to issue a public notice and to deny them the opportunity to demonstrate their treatment is adequate to protect public health.

I. Overview of Niagara's Comments to the Board

On September 25, 2017, we submitted comments to Secretary Patrick McDonnell and the Board objecting to the proposed revisions to § 109.1303. Our comments emphasized the following three points:

1. **Confirmation testing is essential because of the legitimate potential for false positive *E. coli* test results.** 1/ This is why the EPA allows for five additional samples to be tested – to confirm or nullify a fecal indicator-positive initial routine source water sample. 2/ EPA has emphasized that "this limited level of confirmation would not undermine public health protection." 3/ EPA also has explained:

> This prevents systems from incurring costs from the application of unnecessary corrective actions. . . . EPA believes that five additional samples following a positive triggered source water monitoring sample provides a reasonable balance between ensuring that corrective actions are warranted, avoiding excessive resampling costs, and avoiding an incorrect conclusion that the initial positive was false (i.e., avoiding a situation in which corrective action is needed but not taken because of false resample results). EPA believes that multiple samples, rather than one, are needed to ensure that corrective action is taken when necessary. 4/

Until this proposal, Pennsylvania has long elected to provide systems with this opportunity to conduct additional testing on five additional samples within 24 hours. In doing so, Pennsylvania has been in good company, as many other States provide this same allowance. 5/

1/ EPA has stated that it "recognizes that false positive results may occasionally occur with most microbial methods (i.e., a non-target microbe is identified by the method as a target microbe). For example, 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." National Primary Drinking Water Regulations: Ground Water Rule, 65 Fed. Reg. 30194, 30230 (proposed May 10, 2000) (hereinafter "Proposed Ground Water Rule")

2/ *See* 40 C.F.R. § 141.402(a)(3).

3/ Proposed Ground Water Rule, 65 Fed Reg. at 30230.

4/ National Primary Drinking Water Regulations: Ground Water Rule, 71 Fed. Reg. 65574, 65599 (Nov. 8, 2006) (hereinafter, "Final Ground Water Rule").

5/ States that mirror EPA's system of permitting five repeat samples following a single positive source water sample include the following, among numerous others: California (22 Cal. Code Regs. § 64430 (adopting 40 C.F.R. § 141.402)), Connecticut (Conn. Agencies Regs. § 19-13-B102), Florida (Fla. Admin. Code R. 62-550.828 (adopting 40 C.F.R. §§ 141.400-141.405)), Illinois (Ill. Admin. Code tit. 35 § 611.802), Massachusetts (310 Mass Code Regs.§ 22.26(4)), Maryland (Md. Code Regs. § 26.04.01.11-2(D)(8)), New Hampshire (N.H. Code Amin. R. Env-Dw 717.11), New York (N.Y. Comp. Codes R. & Regs. tit 10 § 5-1.52, Table 6), Oregon (Or. Admin. R. 333-061-0032(8)(d)), and Texas (30 Tex. Admin. Code § 290.109(d)(4)(iv)).

Accordingly, due to the possibility of false positives and the associated potential for unnecessary public notifications, Pennsylvania should not delete the provisions in § 109.1303 that allow for five additional samples to be collected within 24 hours following the initial positive sample before requiring corrective action. EPA has determined that this confirmation testing approach provides for adequate public health protection.

2. **Public notice should be reserved for serious situations when contamination has been clearly established.** By eliminating the confirmation testing provisions in § 109.1303, the regulation will require a system that obtains a single initial positive hit for *E. coli* in their source water to comply with Tier 1 public notification requirements under § 109.408. Section 109.408(b) requires that upon detection of *E. coli* in ground water samples, a public notice must be provided "as soon as possible, but no later than 24 hours after the water supplier learns of the . . . situation." The form and manner for the Tier 1 public notice are specified by the regulation and do not make sense for bottled water—particularly when the raw source water that tested positive will undergo a subsequent treatment that will mitigate the potential for *E. coli* in the finished product. 6/ This concern is compounded considering the significant false-positive rate for *E. coli* testing. The rate of occurrence for these public notices will increase under the proposed rule, but there will be no corresponding benefits for public health because any new situations where a notice is made will be situations that would have been ruled out due to subsequent negative testing under the existing regulation. Thus, this proposed rule would not enhance public health, but in fact would cause consumers to discard safe product when there is no reason for concern. 7/

3. **To the extent that the current regulation needs revisions, the regulation should expressly allow for an opportunity to demonstrate 4-log reduction of harmful viruses and bacteria, even when the treatment process has not previously been permitted by the State.** Under the current regulations, if a system has in place a process that provides a 4-log treatment for which the State has issued a permit, § 109.1303 does not apply. However, if a system has in place a process that provides a 4-log treatment for which the Department has not issued a permit (which we refer to in these comments as a "non-permitted system"), but nevertheless is adequate to protect public health, § 109.1303 does apply. Thus, Tier 1 notice can still be required for water that is subject to adequate treatment and poses no risk to consumers. This framework is arbitrary and does not account for the fact that a system may have a robust treatment process in place, even

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6/ 25 Pa. Code § 109.408(d). The State requires use of a standard template that alerts consumers to "Boil Your Water Before Using" and informs them that "boiled or bottled water should be used . . . until further notice." Pennsylvania DEP, *Tier 1 Public Notice for E. coli in a groundwater source without 4-log treatment* (Oct. 2015), *available at* http://www.elibrary.dep.state.pa.us/dsweb/Get/Document-108997/3930-FM-BSDW0150.pdf.

7/ When applied to bottled water, the Tier 1 public notice has the functional effect of a recall, as no one who receives such as notice would want to continue using the affected bottled water. The impact becomes even more significant when considering that consumers and retailers often do not check code dates when discarding product, resulting in significant volumes of safe product being discarded unnecessarily. It does not appear that any of these costs were taken into account when the Board's proposal was developed.

though the State may not have issued (or even have been requested to issue) a permit for the treatment process.

We recommend that the Board revise the regulation to provide that a system have the opportunity to demonstrate to the State, within a reasonable time, that it has an adequate treatment process in place to provide a 4-log reduction of harmful viruses and bacteria. And if the water system can adequately make that showing, no Tier 1 notice (equating to a product recall for bottled water) should apply. This makes practical sense and will avoid the need for public notice to be issued in situations where there is no risk to public health.

II. The Proposed Rule Does Not Satisfy the RRA Criteria for Regulatory Review and Therefore Is Not in the Public Interest

The proposed rulemaking is not in the public interest because it fails to meet the RRA criteria in 71 P.S. § 745.5b. We therefore request that the IRRC submit comments objecting to the revisions to § 109.1303. Below we explain why the proposed rule does not meet the RRA criteria, first repeating the statutory criterion that must be considered by the IRRC and then discussing application of this criterion to the proposed revisions to § 109.1303.

- **71 P.S. § 745.5(b)(1)(i): Economic or fiscal impacts of the regulation, which include direct and indirect costs to the Commonwealth, to its political subdivisions, and to the private sector.**

The Board's proposal would be costly and waste safe bottled water by requiring that water systems conduct corrective actions and engage in public notifications after a single, unverified initial positive *E. coli* sample. Due to the high *E. coli* false-positive rate, this proposed requirement would inevitably result in some systems conducting corrective actions and issuing a public notice when no public health risk exists—i.e., in situations where the initial *E. coli* sample is not confirmed with subsequent sampling. Corrective actions and public notice are both expensive propositions for which the costs would be avoided by keeping the current state regulation in place.

Moreover, consumers will end up disposing of safe bottled water when such notices are issued. This is costly both to consumers and industry. Our concerns with the Tier 1 public notice, which are discussed further later in these comments, are compounded when the opportunity for confirmation testing is eliminated because it is likely that public notices will need to be issued more frequently and, therefore, more safe water will be disposed of. Confirmation testing is an important tool to ensure that corrective actions and public notice are based on good information and, therefore, do not waste money. Indeed, in establishing its own regulation to allow for confirmation testing, EPA determined that such testing prevents systems from incurring costs due to unnecessary corrective actions. 8/ Although the proposed rule is certain to increase costs, there was no discussion or obvious consideration of this as part of the proposal.

8/ Final Ground Water Rule, 71 Fed. Reg. at 65599.

- **71 P.S. § 745.5(b)(2): The protection of the public health, safety and welfare and the effect on this Commonwealth's natural resources.**

Eliminating the provision requiring five confirmation samples does nothing to promote public health. On its face, the Board's proposal to automatically require corrective action and Tier 1 public notification after a single initial positive *E. coli* sample may seem to improve public health protection, but in reality it would only cause unnecessary alarm when no public health risk exists. Due to the false positive rate, requiring confirmation testing provides for more scientifically sound decision-making, while also protecting public health. With a confirmation testing requirement, systems are still required to take corrective action and notify the public if follow-up samples confirm the original positive sample. Public health also is protected because the five follow-up samples must be collected promptly, within 24 hours. Thus, instances of fecal contamination are addressed swiftly, but instances of false positives do not trigger further action that would unnecessarily alarm consumers.

By establishing a framework whereby public notices will be issued more frequently (because confirmation testing will not be available to rule out false positives), the inevitable outcome of the proposal is that the public will receive a health alert in instances where no public health risk exists. This essentially results in crying wolf. Public health is not protected by unnecessary warnings, as consumers may come to ignore them over time. This issue is particularly acute for bottled water, as a public notice does much more than directing consumers to turn off the tap. When consumers receive a public notice about bottled water, their reaction is to throw away all of the product they have on hand—regardless of the brand or production date. Moreover, it would be extremely unlikely for consumers to have product on-hand that is potentially affected by the positive source water test. Production, shipping, distribution, and purchasing would rarely, if ever, be able to all occur within 24 hours of a source water test being conducted. Therefore, consumers will be alerted unnecessarily, which is not protective of public health.

Furthermore, if the proposal is adopted and the number of health alerts increases, consumers could grow distrustful of bottled water. This is not good public policy for many reasons, including because bottled water is a healthy alternative to sugar-sweetened beverages and its consumption should be encouraged. Public notices should only be issued when a public health risk legitimately exists. Accordingly, the Board's proposal to eliminate the use of follow-up sampling would not benefit public health.

- **71 P.S. § 745.5(b)(3)(i): The clarity, feasibility and reasonableness of the regulation, to be determined by considering possible conflict with or duplication of statutes or existing regulations.**

The Board's proposal to discontinue confirmation testing would eliminate a commonsense measure that EPA and numerous other states use to identify false positives. As noted earlier, the preamble to the proposal offers no explanation for the Board's proposal or justification for diverging from the approach followed in numerous other jurisdictions. It is not

reasonable to remove a safeguard against false positives that many states and the federal government consider prudent without even proffering any justification.

- **71 P.S. § 745.5(b)(3)(iii), (v): The clarity, feasibility and reasonableness of the regulation to be determined by considering the need for the regulation and whether acceptable data is the basis of the regulation.**

The Board has not articulated any reason why the existing regulation needs to be revised. There is no problem here that needs to be fixed, which perhaps is why the Board has provided no justification for, nor presented any data to support, its proposal. The IRRC is tasked by the RRC to consider "whether acceptable data is the basis of the regulation," but in this case there simply is no data for the public and the IRRC to assess. The Board's failure to explain the rationale or provide the data upon which its proposal is based has denied the public the opportunity to evaluate the Board's justification for the proposal. This alone should be a reason for the IRRC to object, as failing to provide a rationale is contrary to the fundamental principles of administrative law.

- **71 P.S. § 745.5(b)(3)(iv): The clarity, feasibility and reasonableness of the regulation to be determined by considering the reasonableness of the requirements, implementation procedures, and timetables for compliance by the public and private sectors.**

It is not reasonable to require corrective action and Tier 1 public notification without confirming that the initial sample is indeed positive. The Board's proposal would require systems to conduct a Tier 1 notification within 24 hours of receiving a single initial *E. coli* positive, which would not allow systems adequate time to provide evidence to the State regarding any factors affecting the potential validity of the finding or their subsequent treatment process for the water. When the proposal to eliminate confirmation testing is coupled with the quick-trigger action required for Tier 1 notifications, the proposed regulation would establish a framework that would impose unnecessary costs on systems and waste perfectly safe bottled water without providing commensurate benefits for public health or, indeed, any public health benefit at all.

III. The Current Regulation Also Is Not In the Public Interest, Does Not Satisfy the RRA, and Should Be Revised

Niagara also requests that the IRRC exercise its authority under Section 8.1 of the RRA (71 P.S. § 745.8a) and recommend that the Board revise § 109.1303 to allow systems to demonstrate to the State that they have an effective 4-log treatment system in place for harmful viruses and bacteria that is adequate to protect the public health. As it exists now, § 109.1303 does not apply to systems that have permitted treatment methods in place, but it does apply to systems with non-permitted treatment systems. As we explain below, the current regulation fails to satisfy several of the RRA review criteria and is not in the public interest. The IRRC therefore should recommend that the Board adopt the changes we proposed in our comments to the Board,

provided at Appendix 1, to provide an opportunity for systems with non-permitted treatment methods to demonstrate their effectiveness to the State.

The following RRA criteria are not met:

- **71 P.S. § 745.5(b)(1)(i): Economic or fiscal impacts of the regulation, which include direct and indirect costs to the Commonwealth, to its political subdivisions, and to the private sector.**

The current regulation in § 109.1303 imposes unnecessary costs on industry and wastes natural resources when the system has an effective treatment process in place. The current regulation is unnecessarily costly because it does not give water systems credit for treatment if they have a non-permitted 4-log reduction treatment for harmful viruses and bacteria. The regulation requires a Tier 1 public notification even when water will be treated so that it is safe for public consumption. The unnecessary public notification causes economic harm and unnecessary costs because, for bottled water manufacturers, public notification has the functional effect of announcing a recall. This is costly and wastes safe water. When consumers and retailers dispose of bottled water following a public notification, manufacturers must bear the costs of refunding the retailers and consumers for the product, as well as the sunk cost of affected product in inventory that cannot be sold. These additional costs of Tier 1 public notification put systems with non-permitted treatment methods at a disadvantage to those that have permitted methods, despite the fact that their methods may be equally effective in protecting public health. In addition, the disposal of affected bottled water, despite the absence of any public health risk, amounts to a waste of natural resources. Thus, the current regulation wastes money and safe bottled water, and also creates a competitive disadvantage for systems whose treatment methods, though effective, have not been permitted by the state.

In fact, this very situation happened to our company just 2.5 years ago, in June 2015. At that time, following a finding of *E. coli* in one of the water sources we use, the Department of Environmental Protection required us to make a Tier 1 public notification and resulted in a recall of a significant volume of perfectly safe water (over 38.7 million bottles). This action was required even though we could demonstrate that we had in place a 4-log treatment system that effectively would have killed any harmful viruses and bacteria that may have been present. The rationale provided to us at the time was that the 4-log reduction system had not been officially permitted by the State, so it would not be given any credit. Underscoring the safety of the product, the U.S. Food and Drug Administration designated the recall as "Class III," which means that this is a situation where the product "is not likely to cause adverse health consequences." This massive product recall unnecessarily cost our company approximately $20 million. We do not believe any company should have to bear this severe, negative public impact when the product at issue is perfectly safe.

- **71 P.S. § 745.5(b)(2): The protection of the public health, safety and welfare and the effect on this Commonwealth's natural resources.**

Application of the Tier 1 public notice requirements to systems with non-permitted 4-log treatment provides no benefit to public health. The current regulation requires Tier 1 public notification unless the system has a permitted, 4-log treatment method for viruses. But if a system has an equally effective, non-permitted system in place, Tier 1 public notification is required. There is no opportunity for a system to demonstrate to the State that it has an effective 4-log treatment system that is adequate to protect public health, such that there is no public health need that warrants Tier 1 public notification. Avoiding unnecessary public notices will help ensure that consumers do not become distrustful of such notices.

- **71 P.S. § 745.5(b)(3)(ii): The clarity, feasibility and reasonableness of the regulation to be determined by considering clarity and lack of ambiguity.**

The Tier 1 public notification is confusing when issued by bottled water manufacturers. Currently, the required language of the public notice directs consumers to either boil their water or use bottled water, instructions that are confusing when issued for bottled water. To eliminate this confusion, the Board should develop separate bottled water-specific public notice language to use when bottled water companies issue Tier 1 public notifications. This language should encourage consumers to review the code date of their on-hand product because it may not be affected by the notice. As discussed above, it is unlikely that consumers will have product on-hand that is affected by positive source water findings for *E. coli* because of considerations like production and distribution time, so it is especially important that the rules take these factors into account.

- **71 P.S. § 745.5(b)(3)(iv): The clarity, feasibility and reasonableness of the regulation to be determined by considering the reasonableness of the requirements, implementation procedures and timetables for compliance by the public and private sectors.**

It is unreasonable for the State to require systems with an effective 4-log treatment system to issue a public notice and to deny them the opportunity to demonstrate their treatment is adequate to protect public health. The regulation's current exemption for permitted treatment methods demonstrates that the Board does not consider public notification to be warranted when an adequate treatment system is in place to protect public health. Systems with non-permitted treatment methods therefore should be afforded the opportunity to demonstrate the effectiveness of their systems in a timely manner prior to the State requiring public notification. It is not reasonable for the regulation to deny systems the opportunity to demonstrate that they have an adequate treatment process in place. The need to immediately escalate to a Tier 1 public notice within 24 hours is not necessary to protect public health given the time lag between production and consumer purchase, and therefore a reasonable time should be offered to allow systems to demonstrate that they have an effective process in place to provide treatment.

* * * * *

For the reasons discussed herein, the IRRC should oppose the Board's proposed revisions to § 109.1303 because the proposal is not in the public interest. Additionally, because aspects of this current regulation also are not in the public interest, we encourage the IRRC to exercise its authority under Section 8.1 of the RRA (71 P.S. § 745.8a) and recommend that the Board revise § 109.1303 to allow systems to demonstrate that they have an effective 4-log treatment system in place that is adequate to protect the public health.

Thank you for your consideration. If you have any questions or if we can provide any additional information, please do not hesitate to contact me at bhess@niagarawater.com.

Sincerely,

Brian Hess
Executive Vice President, Legal Affairs
Niagara Bottling, LLC

cc: Fiona E. Wilmarth, Director of Regulatory Review, IRRC
Michelle L. Elliott, Regulatory Analyst, IRRC
James M. Smith, Regulatory Analyst, IRRC
Environmental Quality Board (via RegComments@pa.gov)

Appendix

3177

September 25, 2017

VIA EMAIL TO RegComments@pa.gov

Honorable Patrick McDonnell
Secretary, Department of Environmental Protection
Environmental Quality Board
Rachel Carson State Office Building, 16th Floor
400 Market Street
Harrisburg, PA 17105-8477

RE: Proposed Rulemaking; 25 Pa. Code Ch. 109, Safe Drinking Water; General Update and Fees; 47 Pa. Bulletin 4986 (Aug. 26, 2017)

Dear Secretary McDonnell and Members of the Environmental Quality Board:

Niagara Bottling, LLC appreciates the opportunity to provide comments regarding the Environmental Quality Board's proposed rulemaking addressing the State's safe drinking water regulations in 25 Pa. Code Chapter 109. Family owned and operated since 1963, Niagara Bottling is the leading private label bottled water company in the United States. Niagara has geographically diversified production facilities throughout the United States, including in Pennsylvania. Nothing is more important to us than consumer safety. We are a member of the International Bottled Water Association (IBWA) and are supportive of the comments they are submitting on this proposal.

Pursuant to Pennsylvania's Regulatory Review Act (71 P.S. § 745.5a(a)) we respectfully request notification from the Environmental Quality Board or Department of Environmental Protection (DEP) of any information related to the final-form regulation and the text of the final-form regulation which the State intends to adopt. Please provide us with a copy of the final-form regulation or a copy of all changes to the proposed regulations incorporated into the final-form regulation on the same date these materials are submitted to the Independent Regulatory Review Commission and legislative Committees as specified in 71 P.S. § 745.5a(b).

Our comments focus on the proposed revisions to § 109.1303 of the safe drinking water regulations. The proposed revisions would provide, generally, that if a system has an *E. coli*-positive source water sample, the system would not be given the opportunity to conduct confirmatory testing and instead would be required to conduct corrective actions and comply with the Tier 1 public notification requirements—namely, they would be required to provide a public notice within 24 hours after learning of the positive result.[1] Significantly, the proposal

[1] Although not directly relevant here, current regulations in § 109.1303(g) also provide DEP with the authority, on a case-by-case basis, to invalidate the original *E. coli* positive test findings.

would eliminate the 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, which is an essential step to address the legitimate potential for false positives for this testing. Thus, the Board's proposal will result in unnecessary concern among the public in situations where the water at issue is perfectly safe. We urge you to omit these proposed deletions from the final regulation.

There is very limited discussion in the preamble to the proposed rule regarding the Board's rationale for this significant proposed deletion of confirmation testing in §109.1303. The preamble only states in the introduction that the proposed rule would "[d]elete the provision that allows a PWS to avoid the requirement for a corrective action by collecting five additional source water samples after an *E. coli*-positive triggered source water sample."[2] The lack of explanation is surprising and disappointing given the significant nature of this proposed change. The proposed approach to initial *E. coli*-positives would diverge from the U.S. Environmental Protection Agency (EPA) standard under the Ground Water Rule, Pennsylvania's existing regulation, and the approach taken in many other jurisdictions. Particularly given the lack of proffered justification in this proposed deletion, and thus our inability to provide a meaningful critique of such justification, this significant deletion from the regulations should not be adopted.

As this rulemaking has provided an opportunity to comment on § 109.1303, we also are urging you to consider amending this regulation to recognize the role of treatment to mitigate any potential positive *E. coli* findings that result from the five additional confirmation tests, so long as corrective actions are still taken. Specifically, if a system reliably achieves at least 4-log reduction treatment of viruses and can demonstrate this to the State within a reasonable time, then it should not be necessary to make a Tier 1 public notification. This principle should apply regardless of whether the system previously has received a permit from the State.

Our comments that follow provide background on this provision, explain our concerns, and suggest an alternative approach.

Background and Framework

At the outset, we want to highlight that the current regulation in § 109.1303 provides an important safeguard necessary to account for the real possibility of false positive *E. coli* test results. Therefore, at a minimum, the language in § 109.1303(h)(2) that is proposed for deletion should be retained to allow for five additional *E. coli* tests within a 24 hour period in order to authoritatively determine if the original test result was real or represented a false positive. This is a longstanding and essential safeguard in the system. Additionally, to the extent that the current regulation needs revisions, the changes should address those circumstances when the water system employs a treatment system that effectively safeguards against fecal contamination, even if it has not previously received a permit, so as not to require public notice when there is no real concern about the safety of the water.

[2] Safe Drinking Water; General Update and Fees, 47 Pa. Bull. 4986, 4987 (August 25, 2017).

In our experience, the current approach is that if a source water sample tests positive for *E. coli*, the State allows the water system to collect and test five additional source water samples from the same source within 24 hours of being notified of the positive *E. coli* results. Should the samples all test negative, no further action is necessary – neither corrective actions nor public notification. This is the essential part of the current system that we strongly urge be preserved. Additionally, under current practice, should any of the five additional samples test positive, the State requires corrective action in line with the EPA's decision tree. Tier 1 public notice, under the EPA decision tree also currently is required in the event that the system does not have a treatment process in place that reliably achieves at least 4-log reduction treatment of viruses.

As discussed in more detail in our comments below, it is imperative that § 109.1303 be revised to provide a clear, sensible path to follow in the event of a positive *E. coli* result in source water – both in terms of: (a) allowing for the five follow-on samples to determine is the initial test result represented a true or false positive; and (b) recognizing that a water system may have in place a 4-log reduction treatment system for viruses that has not received a permit from the State, but that still provides adequate public health protection. Especially given that Tier 1 notifications require a public alert to be issued within 24 hours, there should be no ambiguity about how to proceed in these situations. The State's proposed approach, always requiring a Tier 1 notification even when there are five successive negative test results from the same source within 24 hours, does not account for the considerable possibility that the initial result is a false positive. Moreover, public notification should not be triggered when the water system has in place a 4-log reduction treatment system for viruses, as public health is already protected in that circumstance so a notification provides no added benefits.

Confirmatory Testing is Essential to Address Potential False Positives

It is well established that testing methods for *E. coli* can provide false-positive results. EPA has stated that it "recognizes that false positive results may occasionally occur with most microbial methods (i.e., a non-target microbe is identified by the method as a target microbe). For example, 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."[3] This is why the EPA allows for five additional samples to be tested to confirm or nullify a fecal indicator-positive routine source water sample.[4]

EPA has emphasized that "this limited level of confirmation would not undermine public health protection."[5] EPA also concluded that requiring "two fecal indicator-positive source water

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[3] National Primary Drinking Water Regulations: Ground Water Rule, 65 Fed. Reg. 30194, 30230 (proposed May 10, 2000) (hereinafter "Proposed Ground Water Rule"); *see also* W.L. Chao, *Evaluation of Colilert-18 for the detection of coliforms and* Eschericihia coli *in tropical fresh water*, Letters in Applied Microbiology 42 (2006) 115-120, *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1472-765X.2005.01814.x/pdf (finding false-positive and -negative rates for E. coli detection I tropical freshwater samples using Colilert-18 to be 36.4% and 11%, respectively, while for coliform detection the false-positive rate was 10.3%).

[4] *See* 40 C.F.R. § 141.402(a)(3).

[5] Proposed Ground Water Rule, 65 Fed Reg. at 30230.

samples at a site provides strong evidence that the source water has been fecally contaminated."[6] The preamble to EPA's Ground Water Rule explains:

> [U]nless the State determines that corrective action should be taken following an initial fecal indicator-positive source water sample, the final GWR requires that the [system] take five additional samples, and that only if one of those samples is fecal indicator-positive is corrective action required. This prevents systems from incurring costs from the application of unnecessary corrective actions. . . . EPA believes that five additional samples following a positive triggered source water monitoring sample provides a reasonable balance between ensuring that corrective actions are warranted, avoiding excessive resampling costs, and avoiding an incorrect conclusion that the initial positive was false (i.e., avoiding a situation in which corrective action is needed but not taken because of false resample results). EPA believes that multiple samples, rather than one, are needed to ensure that corrective action is taken when necessary.[7]

Until this proposal, Pennsylvania has long elected to provide systems with this opportunity to conduct additional testing on five additional samples within 24 hours. In doing so, Pennsylvania has been in good company, as many other States provide this same allowance.[8]

Our comments on this point are not raising a new issue. In fact, when EPA proposed its Ground Water Rule, "numerous public comments on the proposal expressed concern that a corrective action should not be required based on one source water indicator-positive sample. The rationale for the proposal [requiring collection of five additional samples within 24 hours] was that the likelihood of a false positive result occurring in both the distribution system sample and the fecal indicator source water sample would be small, and therefore it would be likely that the source water positive result was caused by true contamination."[9]

Accordingly, due to the possibility of false positives at the source and the associated potential for unnecessary public notifications, Pennsylvania should not delete the triggered source water monitoring provisions in § 109.1303 that require five additional samples following the initial positive sample before requiring corrective action. We acknowledge that the State has discretion under EPA's regulation to determine that immediate corrective action is necessary; however, the State should have a compelling basis to invoke this provision because the potential implications for an unnecessary immediate corrective action could be substantial. EPA has determined the confirmation testing approach provides for adequate public health protection.

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[6] *Id.*

[7] National Primary Drinking Water Regulations: Ground Water Rule, 71 Fed. Reg. 65574, 65599 (Nov. 8, 2006) (hereinafter, "Final Ground Water Rule").

[8] States that mirror EPA's system of permitting five repeat samples following a single positive source water sample include the following, among numerous others: California (22 Cal. Code Regs. § 64430 (adopting 40 C.F.R. § 141.402)), Connecticut (Conn. Agencies Regs. § 19-13-B102), Florida (Fla. Admin. Code R. 62-550.828 (adopting 40 C.F.R. §§ 141.400-141.405)), Illinois (Ill. Admin. Code tit. 35 § 611.802), Massachusetts (310 Mass Code Regs.§ 22.26(4)), Maryland (Md. Code Regs. § 26.04.01.11-2(D)(8)), New Hampshire (N.H. Code Amin. R. Env-Dw 717.11), New York (N.Y. Comp. Codes R. & Regs. tit 10 § 5-1.52, Table 6), Oregon (Or. Admin. R. 333-061-0032(8)(d)), and Texas (30 Tex. Admin. Code § 290.109(d)(4)(iv)).

[9] Final Ground Water Rule, 71 Fed. Reg. at 65594.

Public Notice Should Be Reserved for Serious Situations When Contamination Has Been Clearly Established

By eliminating the confirmatory testing provisions in § 109.1303, the regulation will require a system that obtains a single positive hit for *E. coli* in their source water to (1) conduct corrective actions (per § 109.1302(c)), (2) comply with § 109.716 (relating to significant deficiencies), and (3) comply with Tier 1 public notification requirements under § 109.408. We are concerned that public notice through Tier 1 public notification is not appropriate or necessary based on a single positive finding that has not been confirmed with additional testing, in light of the significant false-positive rate. The rate of occurrence for these notices will increase significantly under the proposed rule, but there will be no corresponding benefits for public health.

We are particularly troubled by the automatic application of the Tier 1 public notification requirements. Section 109.408(b) requires that upon detection of *E. coli* in ground water samples, a public notice must be provided "as soon as possible, but no later than 24 hours after the water supplier learns of the . . . situation." The form and manner for the Tier 1 public notice are specified by the regulation.[10] The State requires use of a standard template that alerts consumers to "Boil Your Water Before Using" and informs them that "boiled or bottled water should be used . . . until further notice."[11]

In light of the high false-positive rate for *E. coli* tests, such notifications are certain to result in situations where consumers are put on alert even though there is no public health concern. Furthermore, such a notice has the functional effect of a recall, as no one who receives such as notice would want to continue using the affected bottled water. The issue is compounded when considering that consumers and retailers often do not check code dates when discarding product, resulting in significant volumes of safe product being discarded unnecessarily. It does not appear that any of these costs were taken into account when the proposal was developed.

The short time permitted for public notification under the rule also limits the ability to involve outside experts, such as bottled water subject matter experts from the U.S. Food and Drug Administration (FDA), to make a case-by-case assessment of whether the water will be subject to an adequate treatment to address any contamination that may have been present in the source.[12] The regulation would benefit from providing an opportunity for evaluation of the

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[10] 25 Pa. Code § 109.408(d).

[11] Pennsylvania DEP, *Tier 1 Public Notice for E. coli in a groundwater source without 4-log treatment* (Oct. 2015), *available at* http://www.elibrary.dep.state.pa.us/dsweb/Get/Document-108997/3930-FM-BSDW0150.pdf. We also want to use this opportunity to note that substantively the required language of the Tier 1 notice does not make sense when issued by a bottled water manufacturer who also falls under these regulations because they are regulated as a public water system in Pennsylvania. Alerting consumers to avoid use of this bottled water and instead use bottled water is not helpful. The Department should develop a model alert that is specific to the numerous bottled water manufacturers in Pennsylvania who also fall under the public water system regulations.

[12] In 2015, Niagara Bottling conducted a recall when one of our contracted springs failed to notify us that there was evidence of *E. coli* bacteria at the spring source. Had Pennsylvania's regulations permitted us to provide documentation of the process we had in place to provide a 4-log treatment for viruses, the resulting recall would not have been necessary.

situation prior to the need to issue public notification. Thus, this proposed rule would not enhance public health, but in fact would cause consumers to discard safe product when there is no reason for concern. The requirement to engage in a Tier 1 notice should be reserved for serious situations where there is certain to be an *E. coli* issue, the potential for false-positives has been ruled out, and the water system does not already have in place a treatment process that achieves a protective 4-log reduction for viruses.

The Regulation Should Allow for an Opportunity to Demonstrate 4-Log Reduction of Viruses, Even When a Permit for the Process Has Not Previously Been Issued by the State

Under the current regulations, if a system has in place a system that provides a 4-log treatment of viruses for which the Department has issued a permit, § 109.1303 does not apply. However, if a system has in place a process that provides a 4-log treatment of viruses for which the Department has not issued a permit, but nevertheless is adequate to protect public health, § 109.1303 does apply. Thus, Tier 1 notice can be required for water that is subject to an adequate treatment. This framework is arbitrary and does not account for the fact that a system may have a robust treatment process in place, even though the State may not have issued (or even have been requested to issue) a permit for the treatment process.

We recommend revising the regulation to provide that a system has the opportunity to demonstrate to the State, within a reasonable time, that it has an adequate treatment process in place to provide a 4-log reduction of viruses. This makes practical sense and will avoid the need for public notice to be issued in situations where there is no risk to public health. We recommend that this evaluation take into account input from outside experts, such as bottled water subject matter experts from the FDA to make a case-by-case assessment of whether the water will be subject to an adequate treatment to address any contamination that may have been present in the source.

Importantly, should a system be able to demonstrate that they have an adequate treatment process in place, it should still be required to perform corrective actions. This step is essential to mitigate any future *E. coli* concerns in the source water, ensuring that the root cause of the contamination is addressed. In this way, the role of treatment serves to avoid crying wolf about safe water, without allowing a source requiring remedial action to be used without implementation of corrective measures.

The Proposal Should Not Be Adopted Without Significant Revisions

We urge the Board to reconsider its recommendation to revise § 109.1303. As discussed above, the proposal would eliminate the important ability to conduct confirmation testing, result in unnecessary public concern for safe water, and push Pennsylvania's regulations out of alignment with other State jurisdictions and the federal government. Additionally, the proposed rule fails to address the equally important situation where an existing 4-log treatment program for which the State has not issued a permit negates the need for public notification.

Accordingly, we encourage the Board to maintain the existing provision of § 109.1303, allow for five successive tests, and to initiate rulemaking to further revise this provision as follows:

- Keep the regulation in line with current practices and provide that collecting five additional samples within a 24 hour period as confirmatory testing is allowed following a positive *E. coli* result received under § 109.1303(a);
- Recognize that a system may have in place for the source water a 4-log treatment of viruses for which the Department has not issued a permit but is adequate to protect public health; and
- Acknowledge that a Tier 1 public notification is not necessary if the confirmation testing is negative or the system can demonstrate that it has adequate treatment in place.

Taken together, the revisions to § 109.1303(h) would read as follows (with new language underlined and deleted language marked with strikethrough):

> (h) For an *E. coli*-positive source water sample collected under subsection (a) that is not invalidated under subsection (g):
>
> (1) The Department may require a groundwater system to perform a corrective action as described under § 109.1302(c) (relating to treatment technique requirements).
>
> (2) If the Department does not require corrective action under § 109.1302(c), the system shall collect five additional source water samples from the same source within 24 hours of being notified of the *E. coli*-positive sample. If one of the additional samples collected under this paragraph is *E. coli*-positive, the groundwater system shall (i) perform a corrective action as described under § 109.1302(c), and (ii) have the opportunity to demonstrate to the Department within a reasonable time that the water shall be subject to treatment that reliably achieves at least 4-log reduction of viruses before the first customer for the groundwater source.
>
> (3) If any of the five additional source water samples collected under subsection (h) are positive and the system has not demonstrated adequate treatment to reliably achieve at least 4-log reduction of viruses as provided under subsection (h)(2), ~~T~~the system shall comply with Tier 1 public notification requirements under § 109.408 (relating to Tier 1 category, timing and delivery of notice).

These proposed revisions would maintain the confirmation testing provision, eliminate ambiguity about the need for corrective actions and public notice, and allow a system to demonstrate that they have adequate treatment in place to mitigate the need for a Tier 1 public notification even when the 4-log treatment process has not previously been submitted to the State. Additionally, we want to highlight that corrective actions would be required in the event that an appropriate treatment process is in place to mitigate any future the *E. coli* concerns in the source water, ensuring that the root cause is addressed. Taken together, these revisions would make the regulation more practical, protect public health, and eliminate the need for unnecessary public concern about safe water.

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Niagara Bottling is strongly committed to producing safe bottled water for our consumers. Thank you for your consideration of our comments. If you have any questions or if we can provide any additional information, please do not hesitate to contact me at rschwaner@niagarawater.com.

Sincerely,

Ryan Schwaner
Vice President, Quality and Food Safety
Niagara Bottling, LLC