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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 I 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 if 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

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 Escherichia 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 in 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.

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 Admin. 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 a 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

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), ~~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 rschwane@niagarawater.com.

Sincerely,

A handwritten signature in black ink, appearing to read "William Ryan Schwaner". The signature is fluid and cursive, with the first name "William" being the most prominent.

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