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DATE: December 20, 2018

TO: Hearing Attendees and Commenters –
Oregon Administrative Rule 333-061-0510 through 0580: "Cyanotoxin
monitoring and public notification at public drinking water systems"

FROM: Brittany Hall, Hearing Officer

cc: David Emme, Section Manager
Drinking Water Services

Kari Salis, Technical Manager
Drinking Water Services

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public
Comment Period

Hearing Officer Report

Date of Hearing: November 27, 2018

Purpose of Hearing: To receive testimony regarding the Oregon Health Authority (OHA), Public Health Division's proposed permanent adoption of Oregon Administrative Rules 333-061-0510 through 0580 relating to testing for cyanotoxins at subject water systems and public notification if advisory levels are exceeded.

Hearing Officer: Brittany Hall

OHA greatly appreciates all the comments received and the time and effort water suppliers spent reviewing these rules. The attention to detail and specificity of the comments were very helpful in establishing regulations that balance public health protection, ease of implementation, and cost effectiveness.

Testimony Received: Two individuals provided oral testimony at the hearing. Their comments are briefly summarized below.

1. Jessica Dorsey, Joint Water Commission

Ms. Dorsey stated that the Joint Water Commission (JWC) would be submitting written comments but highlighted some of the Commission's concerns in her oral testimony.

She testified that the JWC has concerns about the requirement for qPCR testing and that the JWC believes the science has not yet found that qPCR for cyanotoxin-producing genes can be a reliable predictor of toxin occurrence. She opined that it may be more practical for the testing requirements to focus on the toxins themselves. While this could be a technology used in drinking water, more study needs to be done before mandating in administrative rule that qPCR technology be used for testing.

Ms. Dorsey testified that the JWC feels that the need for weekly testing requirements in the summer and testing requirements in the winter hasn't been established based on data collected during the temporary rule monitoring period in 2018. She opined that monitoring every two weeks during the summer monitoring period from May to October is sufficient.

Ms. Dorsey testified that the JWC feels that a clause of the rule related to triggers of gene count per mL requiring finished water testing does not seem to be in line with the current understanding of PCR's abilities. She opined that it would make more sense for greater than 2500 gene counts per mL in raw water to require raw water toxin testing rather than finished water toxin testing.

a. Agency Response:

Several commenters expressed concerns about including qPCR testing for cyanotoxin-producing genes in regulation, due to increased complexity of the rules, limited data, and potential issues with methodology and lab accreditation. OHA has removed all requirements related to monitoring for cyanotoxin-producing genes from the final rule. What remains is that susceptible sources must monitor for cyanotoxins every two weeks between May and October. OHA believes that qPCR analyses for cyanotoxin-producing genes holds promise as a reliable and cost-effective indicator of the potential for cyanotoxins. However, OHA acknowledges that the cost was high, and we lack Oregon-specific data on correlation of cyanotoxin-producing genes and cyanotoxins, typical lag times of presence of toxins following a gene detection, risk of cyanotoxins in winter months, and any correlation data specific to cylindrospermopsin. Further, criteria to determine whether a source is potentially susceptible was based on limited data, and therefore the likelihood of a public health threat from cyanotoxins in these sources is less known.

For these reasons, OHA is seeking funding for a statewide water quality study to gather data similar to the monitoring requirements in the proposed rules. This data may be used to inform future rule revisions. It may also inform whether a particular source

should be considered susceptible such that the regulatory requirements apply. OHA is hopeful that water suppliers will assist us in conducting this study by collecting samples when requested.

Ms. Dorsey also submitted written comments on behalf of **Kevin Hanway**, General Manager of the Joint Water Commission, attached to this report as "Exhibit 1".

Mr. Hanway's written comments state that the Joint Water Commission appreciated the opportunity to comment on the proposed permanent cyanotoxin monitoring rule and provide "necessary considerations to ensure the permanent rule provides a benefit to public health but also is not an undue burden on the state, drinking water providers, and the citizens they serve." Mr. Hanway provided specific comments on various rules:

1. **OAR 333-061-0540(2)(a)(A)(ii) and OAR 333-061-0540(2)(a)(B)**: Request for the removal of required monitoring using qPCR. Reasons for this request are detailed in the written comments.
2. **OAR 333-061-0540(2)(a)(B)**: Clarifying language is recommended in the written comments to be consistent with other aspects of the rule that have requirements for follow-up sampling timing, should the agency move forward with the qPCR requirement.
3. **OAR 333-061-0540(2)(b)(A)**: Recommendation for the removal of paragraph (A) in subsection (2)(b) regarding cyanotoxin-producing gene counts at the raw water sampling point. Reasons for this recommendation are detailed in the written comments.

b. Agency Response:

For numbers 1 through 3, see above Agency Response (a), related to removing the qPCR requirement.

4. **OAR 333-061-0550(3)**: Recommendation for the removal of section (3) regarding analysis method for follow-up samples when dealing with concentrations above the health advisory. Reasons for this recommendation are detailed in the written comments.

c. Agency Response:

There is currently no federal EPA standardized method for analysis of cylindrospermopsin using the ELISA technique. However, this technique has been proven reliable, faster, and more cost-effective than liquid chromatography double mass spectrometry. In the case of cylindrospermopsin, the ELISA method and EPA method 545 are looking for the same constituents, just using different methods. To make the

high-impact decision of whether to issue a do-not-drink advisory, OHA and DEQ feel it is important to have at least one result analyzed by a standardized EPA method. In order to use the same method for each sample we would need to use LC MS/ MS each time, which would be more expensive and take longer to get results and thus is not desirable.

5. **OAR 333-061-0560(2)**: Statement that the requirements for analysis and direct reporting by labs stated in section (2) should be part of the accreditation described in OAR 333-061-0550(1) since lab methodology is not overseen by providers.

d. Agency Response:

Several comments were received regarding the need for water suppliers to ensure that laboratories meet the analytical timing and reporting requirements and stated that these requirements should fall under ORELAP accreditation criteria. ORELAP rules are for analytical techniques and not reporting. OHA-DWS has no jurisdiction over labs other than reporting results that exceed a Maximum Contaminant Level or a Health Advisory Level. OHA believes it is reasonable to suggest that water suppliers only work with labs that are capable of meeting the required analytical and reporting times. This is generally consistent with reporting requirements for other regulated contaminants. The DEQ lab is capable of meeting these timelines, assuming adequate funding is available.

6. **OAR 333-061-0570(1)(a)**: Recommendation of the addition of "entry point" to this subsection for clarification.

e. Agency Response:

Clarification made.

7. **OAR 333-061-0570(5)(b)**: Request that the requirement to report raw water gene counts in the consumer confidence report be removed. Reasons for this recommendation and proposed text changes are detailed in the written comments.

f. Agency Response:

Regarding inclusion of results from raw water in a water supplier's annual Consumer Confidence Report, OHA performed a more detailed review and interpretation of OAR 333-061-0043 and agrees that the intent is to report detections of any contaminant that may pose a public health threat. Contaminants found in raw water, though regulated, do not pose a public health threat unless found in treated water. OHA has modified the rule language to only require reporting of detections found in treated water, consistent with other regulated contaminants.

8. **OAR 333-061-0570(6)**: Request that information be included "on uses that are affected by an advisory (drinking, cooking, bathing, etc.) as this was an issue of public concern during the 2018 advisory issued by the City of Salem and OHA is the appropriate agency to develop standard guidance on this."

g. Agency Response:

Several commenters noted that more information than required in the public notification section 333-061-0570 would be useful in the event of an advisory. OHA believes that requiring the concentrations detected, the source of the contaminant, persons affected, and standard health effects language is consistent with public notice requirements of other contaminants. These are minimum requirements. EPA has a risk communication toolkit that can be very useful should an advisory be needed. Additional information may be added to any advisory that the water supplier feels clarifies or further explains the situation. OHA would work with any water supplier needing to issue an advisory. Recommended language may change over time, hence OHA has kept the public notification content to a minimum.

Mr. Hanway's written comments also state that the Joint Water Commission "supports an expansion to the state HABs [harmful algal blooms] monitoring program as an effort to better understand the risks HABs pose to public health in Oregon by impacting recreation, agriculture, and ecosystems, as well as drinking water."

2 (oral). Joel Cary, Tualatin Valley Water District/Oregon Water Utility Council

Mr. Cary stated that the Oregon Water Utility Council (OWUC) would be submitting written comments as well but highlighted some of the points in his oral testimony, summarized below.

Overall, OWUC has concerns about the complexity of the rules in general. He opined that they are rather complicated for a lot of utilities to interpret and can make it challenging for some utilities to see the value of some of the monitoring required. He stated that OWUC would push to see some simplification of the rules.

Regarding the applicability or the use of 303d list of impaired water bodies, Mr. Cary stated that OWUC has concerns that some systems are being categorized in this rule that shouldn't be.

Like Ms. Dorsey, Mr. Cary testified that qPCR is not a valid way to assess cyanotoxin blooms without further evaluation across the state, and without further research into that method and long-term assessment to understand the validity of it. He opined that there

are still concerns about the testing methodology being used and concerns of post-treatment processes that highlight that there is potential for detections, including potential post-oxidation cyanotoxins that can show up in the methods that are 100 times less toxic.

Agency Response:

Oral comments summarized the written comments submitted by the Oregon Water Utility Council. See responses below.

Other Comments: Fifteen individuals submitted written comments to the Division within the period allotted for public comment. These comments are briefly summarized as follows:

2 (written). Karen Kelley, Chair, Oregon Water Utility Council; Michael Grimm, Vice Chair, Oregon Water Utility Council; Joel Cary, Secretary, Oregon Water Utility Council; Tracy Rutten, League of Oregon Cities; Mark Landauer, Special Districts Association of Oregon

The Oregon Water Utility Council, League of Oregon Cities and Special Districts Association of Oregon submitted a joint letter to "seek additional clarification on the proposed rules, provide further expertise from members, and see the adoption of a rule that provides meaningful public health protection for the communities most at risk." Their letter also includes an attachment of suggested edits to the proposed rules in tracked changes to be used in combination with the letter.

Among general comments on the proposed rules, the letter states that "utilities remain concerned about the complexity of this rule." The letter requests that "every effort should be made to first, simplify these rules and second, develop guidance and training to assist utilities of all sizes to comply." The letter further details comments on specific rules:

OAR 333-061-0510: Applicability of Cyanotoxin Rules

The letter states that "use of the 303(d) list of impaired water bodies as a single factor in determining whether an intake is susceptible or potentially susceptible to harmful algal blooms (HABs) or release of cyanotoxins is not supported....Use of the 303(d) list should be part of a matrix used in thoughtfully considering the risk of HABs/cyanotoxins in that water body instead of a single check to determine susceptibility." Further details to support these statements are provided in the letter.

a. Agency Response:

Ms. Kelley suggests that many other factors need to be considered when determining a source to be susceptible to cyanotoxins in addition to the Clean Water Act 303(d) listings. OHA and DEQ agree that many other factors, including those listed by the

commenters, can factor in to determining susceptibility for HABs/cyanotoxin production. However, resources and capacity for the state to conduct the necessary analyses are not in place to so do. We note that the rules provide a mechanism by which water systems can propose exemption from required monitoring according to an examination of many of the same factors mentioned in the comment.

While we recognize the concern over use of the 303(d) list a primary factor for identifying susceptible waterbodies for HABs, and lacking a statewide monitoring plan for HABs detection, we note that data used for these evaluations provide the only current way to consistently evaluate levels of susceptibility statewide. Although the commenter offers a general alternative approach to make use of the 303(d) list, a specific alternative mechanism was not provided.

In removing the qPCR monitoring requirement in the final rule as noted in responses to other comments, cyanotoxin monitoring requirements only apply to susceptible sources, which include sources with a history of harmful algae blooms or cyanotoxin detections or are on the 303(d) list for algae and aquatic weeds. Sources on the 303(d) list due to other parameters are no longer considered susceptible and subject to monitoring requirements under current regulation.

OAR 333-061-0540: Cyanotoxin Monitoring

The letter provides the recommendation to remove the requirement to sample for qPCR and details reasons for this recommendation.

b. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of the qPCR requirement.

OAR 333-061-0550: Analytical Methods

Two points are provided in the letter regarding the requirement for analyzing samples using the ELISA method, but then reanalyzing samples where detections are found using the EPA Method 545, stating that "the two methods cannot be directly compared as they are not looking at the same things."

c. Agency Response:

See above response to Commenter (1), Agency Response (c) regarding analytical methods when confirming a cylindrospermopsin result.

The comment also opines that using the ELISA analytical method post-oxidation can lead to false positives of toxins and is therefore misleading.

d. Agency Response:

According to the US Environmental Protection Agency (EPA), false positives were not detected at any significant rate during the development of Method 546. The article cited in the comment speculates that oxidized microcystin congeners could retain enough of the ADDA portion of the microcystin to be recognized by the ELISA-ADDA method 546. However, this bias was not seen in performance data during method development. EPA also states that oxidation of a microcystin molecule can make the molecule less toxic, but still toxic, thus should not be considered a false positive. It is possible that Method 546 could detect non-biologically active microcystin disinfection by-products, though again this did not emerge to a statistically significant level during method development. EPA also acknowledges that there is a small concern regarding disinfection by-products affecting microcystin quantitation using method 546, but it is still the best method for detecting total microcystins.

The letter further questions "How does OHA intend to adapt and improve this rule as significant developments are made in understanding cyanotoxin testing?" and provides an example in support of the rapidly evolving science surrounding cyanotoxins. The letter also questions "has OHA considered the unintended public health impacts of a 'do not drink' advisory to vulnerable populations who may then be at risk from moderate or severe dehydration when it's potentially unclear what degree of actual microcystin toxins or non-toxic biodegradation products are present?"

e. Agency Response:

If new significant findings or federal regulation are presented, Oregon's rules may be modified through a public process. Currently, the best available science indicates that the most protective way to respond to cyanotoxin levels above a health advisory is to issue an advisory to the affected population stating that the water is not safe to drink, and an alternate source of water should be found.

OAR 333-061-0560: Reporting

The letter states that OAR 333-061-0560 says "The water system must ensure that laboratories...." and provides specific requirements for direct lab reporting, lab sample validation timelines, and laboratory reporting methods. The letter questions why the cyanotoxin rules are calling for utilities to manage laboratory practices when laboratories are responsible for meeting those requirements in OAR 333-061-0040, with the water systems being responsible for assuring reporting occurs within the specified reporting period.

f. Agency Response:

See above response to Commenter (1), Agency Response (d) regarding reporting requirements.

OAR 333-061-0570: Public Notification

The letter questions why raw water detections are included in the requirements for consumer confidence reports (CCR), and further states that "standard practice for reporting detections in the CCR are for samples with action levels, maximum contaminant levels, etc., which for cyanotoxins are entry point samples." The letter states that communicating this data to the public will "likely lead to significant confusion amongst the public about the safety of their drinking water."

g. Agency Response:

See above response to Commenter (1), Agency Response (f) regarding reporting of raw results in the Consumer Confidence Report.

These individuals' written comments are attached to this report as "Exhibit 2".

3. Chris Bailey, Public Works Operations Director, City of Albany

Ms. Bailey wrote that "we [the City of Albany] share the concern of potential harmful algal bloom impacts on public drinking water and support further research to better understand the public health and water system operation implications." Her written comments also include an attachment of suggested edits to the proposed rules in tracked changes to be used in combination with her letter.

Ms. Bailey provided similar comments as the Oregon Water Utility Council, League of Oregon Cities and Special Districts of Oregon above regarding the following rules:

OAR 333-061-0510: Applicability of Cyanotoxin Rules – Concern "about the use of the 303(d) list of impaired water bodies as a single factor in determining whether an intake is susceptible or potentially susceptible to harmful algal blooms (HABs) or release of cyanotoxins." Her written comments provide details to support this concern.

a. Agency Response:

See above response to Commenter (2 - written), Agency Response (a) regarding use of the Clean Water Act 303(d) listings to determine susceptibility to cyanotoxins.

OAR 333-061-0540: Cyanotoxin Monitoring – Concern that "the health advisory level is at the minimum detection level for total microcystin...because it does not allow for early detection of microcystin in the water." In addition, recommendation that qPCR sampling be removed from the proposed rules. Her written comments provide details to support this concern and recommendation, and to "encourage OHA to work with researchers to develop a study to provide the necessary data in Oregon by which to make decisions on the use of qPCR as a sampling tool."

b. Agency Response:

OHA acknowledges that having a method detection limit match that of the health advisory level is not desirable, however Method 546 is the best available method to measure total microcystins.

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

OAR 333-061-0560: Reporting – Recommendation that language in section (2) regarding responsibility for direct lab reporting timelines, reporting methods, and sample validation timelines be revised to match more closely with OAR 333-061-0040 so that the requirements are put upon the laboratories and not the water utilities, since water utilities do not have control over any laboratory practices and only have control over the lab they contract with and are responsible for assuring the lab is accredited.

c. Agency Response:

See above response to Commenter (1), Agency Response (d) regarding reporting requirements.

OAR 333-061-0547: Public Notification – Regarding Consumer Confidence Reports, recommendation that the language about reporting raw water samples be removed from OAR 333-061-0547 to be consistent with OAR 333-061-0043 because the "requirement to report raw water sample results when the action level is based on entry point results will be confusing to customers and is contradictory to OAR 333-061-0043."

d Agency Response:

See above response to Commenter (1), Agency Response (f) regarding reporting of raw results in the Consumer Confidence Report.

Ms. Bailey's written comments are attached to this report as "Exhibit 3".

4. Greg Ford, Phytoxigene, Director of Business Development, North America

Mr. Ford provided feedback and clarification on two rules:

OAR 333-061-0520: Definitions – In reference to the Microcystin Gene Cluster referred to in section (3), he noted that the cluster is about 15 separate genes and the CyanoDTec assay targets specifically the McyE gene. Providing additional information, including a resources page on his company's website that has a list of 25 publications that reference the use of the McyE gene and other targets within the cluster (<https://www.phytoxigene.com/resources/>), he stated that he "bring[s] this up as one

scientist thought they have have [sic] to screen for the entire cluster. While this is feasible, it is not simple or fast and not conducive to a routine monitoring program."

a. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

If cyanotoxin-producing genes are included in future regulation, OHA will utilize results from our study and other relevant studies as well as confer with EPA experts to determine the most appropriate gene targets.

OAR 333-061-0540: Cyanotoxin Monitoring – Citing the reference to "a gene threshold of 2500 gene copies/ml" listed for any of the toxin genes that are being monitored for, Mr. Ford highlighted that "the state of Ohio established a threshold of 5,000 gene copies per ml only for the McyE gene (microcystin)." He opined that "given that some Oregon water systems frequently have cylindrospermopsin toxins, I imagine that you will soon generate data that will allow you to establish a reliable threshold number where you will be at the lower level of detection for the toxin itself" and further opined that "it would be better to be conservative and use a lower number for CyrA and SxtA genes at the start of the program."

b. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

If cyanotoxin-producing genes are included in future regulation, OHA will utilize results from our study and other relevant studies as well as confer with EPA experts to determine appropriate gene thresholds to trigger cyanotoxin monitoring.

Mr. Ford's written comments are attached to this report as "Exhibit 4".

5. Mark Van Asten, Phytoigene

Mr. Van Asten provided his comments in response to Mr. Ford's above, opining that Mr. Ford made relevant points, but added more detail and references specific to the discussion. He also provided some tables to support his comments, including a table "that lists some of the past papers that reference different microcystin [sic] gene targets, and while most papers conclude there is value in the respective target, it is also important to note that the targets [sic] sequences that these papers utilise are specific to one of the genus's of one microcystin producers...they utilised specific mcyE probes for 3 different genus of cyanobacteria to demonstarte [sic] utility in using qPCR." Regarding

gene threshold trigger, he indicated that no other studies have validated a specific level. While most papers highlight a correlation between gene count and toxin levels, none have compiled enough data to validate a specific number to that target.

Providing some specific information about technology that his company developed around the MycE gene and providing a table that highlights the list of species his company has tested, he opined that "it may be advisable to insure that the laboratories utilise an assay that can detect a wide range of microcystin producers."

Agency Response:

See above response to Commenter (4).

He stated that "while we are of course highlighting the advantages of our technology, and it could seem biased, the underlying purpose of sharing this information is to make you aware of the many issues that need to be assessed when considering recommendations for the utilization of a PCR assay to screen and discriminate a toxic and non-toxic cyanobacteria producer."

Mr. Van Asten's written comments are attached to this report as "Exhibit 5".

6. Dwayne Barnes, Utility Operations Manager, City of Salem, Public Works Department

Mr. Barnes wrote that the City of Salem has concerns that the ORELAP Certification Process will not be able to certify certain laboratories by the time the rule is implemented. As such, he requested that OAR 333-061-0550(1) Analytical Methods and Analytical Times, be deleted from the proposed rules. He further wrote that "we assert 333-061-0550 (2) through (4) adequately assure analysis performance to industry standards by defining specific EPA approved methods for analysis of total microcystins, cylindrospermopsin, and cyanotoxin-producing genes."

Mr. Barnes' written comments are attached to this report as "Exhibit 6".

Agency Response:

Use of ORELAP-accredited labs is standard for all regulated contaminants and OHA does not see a compelling reason not to do so for cyanotoxins. OHA is prepared to accredit any labs that wish to go through the ORELAP-accreditation process for any methods required in the rule. The DEQ lab is also prepared to conduct all analysis required by this rule. There was a concern that the standardized method for qPCR may not be ready by May 2019, but OHA has removed all requirements to test using qPCR from the final rule.

7. Yone Akagi, Water Quality Manager, Portland Water Bureau, City of Portland

Ms. Akagi's written comments provide general questions and comments from the Portland Water Bureau (PWB) for OHA's consideration:

She stated that PWB has concerns about the accuracy of the estimated costs that OHA provided for the analysis of cyanotoxins and cyanotoxin-producing genes given that: "a) the methods have not been finalized, b) no other labs are certified by Oregon for analysis using the methods referenced in this rule, and c) future DEQ funding to provide analytical services under this rule and staffing of their lab for these analyses is uncertain." She further stated that "PWB is concerned that costs for compliance may vary considerably going into the future."

a. Agency Response:

OHA acknowledges that the overall cost of cyanotoxin monitoring in the proposed rule is substantial. As mentioned elsewhere in this document, OHA is limiting the applicability of the final permanent rule to susceptible sources only and limiting cyanotoxin monitoring to every two weeks between May and October. If no detections are found, this is estimated to cost \$3,120 per source per year, or \$180,000 for the total cost statewide per year. The proposed rule would have cost \$400,000 per year.

OAR 333-061-0520: Definitions

(3)

- *cyr A* gene is misspelled as "cyI"
- Citing information about the inclusion of the *mcy* gene cluster in the definition of cyanotoxin-producing genes, indicating that the gene cluster spans 55 kilo bases, including 10 genes, Ms. Akagi questioned if it's necessary to test for the entire *mcy* cluster? She opined that "requiring analysis for the complete *mcy* cluster rather than one or two specific genes within the cluster is likely to have significant impacts on the cost and time to complete the analysis." She provided some recommended language to address these concerns: "Cyanotoxin-producing genes means cyanobacteria genes that are necessary to produce microcystins and cylindrospermopsin," with specific genes being defined within the method.

b. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

(5)

Ms. Akagi wrote that "detected" or "detection" refer to the method reporting limits (MRLs), which are different for each method. Citing that a threshold value of 0.3 µg/L is used throughout the proposed text, she opined that "it is confusing throughout the rules as to when 0.3 µg/L refers to a general threshold and when it refers to a HAL [health advisory level]."

c. Agency Response:

OHA acknowledges that 0.3 ppb being a detection limit for total microcystins, a trigger for additional monitoring, and a health advisory level is confusing. In the rule language, where 0.3 ppb is specifically stated, it references a trigger for additional monitoring of total microcystins and cylindrospermopsin. Detection limits and health advisory levels are stated as such.

OAR 333-061-0540

(2)(a)(A)(ii)

Ms. Akagi requested an explanation for the selection of the qPCR threshold of 2500 gene copies/mL. She also requested that the agency consider changing "counts" to "copies" throughout the proposed rules.

(2)(b)(A) and (3)(a)(A)(ii)

Ms. Akagi provided specific requested edits to these rule parts in her written comments.

d. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

(2)(b)(B)

Ms. Akagi requested that the agency consider "allowing weekly entry point cyanotoxin monitoring to begin within 24 hours or within *one business day* of receiving raw water cyanotoxin results that are above 0.3 ug/L.

e. Agency Response:

If cyanotoxins are detected at an entry point, OHA believes the situation is urgent enough to warrant additional sampling within 24 hours. If extenuating circumstances apply, there is a provision that allows OHA to extend the monitoring timeline required upon request.

(2)(a)(B)(i) and (3)(a)(A)(i)

In reference to detection of cyanotoxin producing genes, Ms. Akagi requested that the lower limit of detection be defined to avoid false positives.

(3)(a)(A)(i)

Ms. Akagi questioned "what is the trigger to return to monthly monitoring of cyanotoxin-producing genes" if detection triggers biweekly monitoring?

f. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

(4)(b)

Ms. Akagi provided suggested edits to subsection (4)(b) to clarify intent regarding distribution sampling.

g. Agency Response:

Clarifications made. Each water system on an advisory must sample in their distribution system in order for the advisory to be lifted.

OAR 333-061-0550: Analytical Methods and Analytical Times

Ms. Akagi wrote that the PWB "has significant concerns that the DEQ methods listed have not been published and provided with other rule materials for review as part of the public comment period." She opined that the "methods, associated materials, and analysis times, are a critical part of implementation and compliance with this rule, and as such should be included with the review materials."

In regard to this rule, Ms. Akagi also opined that the title of the rule "could be misleading as it does not provide required analytical times for each method listed." She requested that the agency "consider stating maximum analysis times within which each method shall be completed," rather than specifying times in the reporting section.

h. Agency Response:

Because the analytical times allowed in the method are longer than appropriate to ensure that public health is protected, OHA limited the time for a lab to analyze and report the results of the sample due to the health effects associated with a high result. Regulating analytical times separately from reporting times would make the rules more complex and redundant, so OHA chose to simply regulate reporting timelines. Water suppliers would need to work with a lab, such as the DEQ lab, that is capable of meeting these timelines.

(3)

Ms. Akagi questioned if DEQ was providing analysis under EPA Method 545, what the estimated cost for the analysis is, and whether DEQ is working with other labs to gain accreditation by Oregon to perform this analysis?

i. Agency Response:

As stated in the Fiscal Impact Statement, the estimated cost to analyze for total microcystins and cylindrospermopsin is \$240. The DEQ lab is prepared to conduct all analysis required by this rule, assuming adequate funding is available. OHA is also prepared to accredit any labs that wish to go through the ORELAP-accreditation process for any methods required in the rule.

OAR 333-061-0560

Ms. Akagi wrote that the PWB suggests, for clarity, that this rule be divided "such that the reporting timeframe is based on the implication/type of result." She opined that it "is not clear what reporting timeframe is required for a raw water cyanotoxin result."

j. Agency Response:

Some clarifications were made to this section. OHA believes it is most appropriate to indicate reporting times based on the result of the sample. This is consistent with other parts of drinking water rules that require labs to report results above a maximum contaminant level within 24 hours.

(2)(a) & (b)

Ms. Akagi opined that the turnaround time of 48 hours of reporting for qPCR may be unrealistic due to the increased scope of targeted genes for microcystins (*mcy* gene cluster). She requested that the agency consider "separating time requirement for gene validation/reporting from cyanotoxin reporting since they have different implications for compliance and public health protection."

k. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

(2)(e)

Ms. Akagi requested that the agency reword this subsection, providing specific language in her written comments.

l. Agency Response:

Clarifications were made to this subsection.

Ms. Akagi's written comments are attached to this report as "Exhibit 7".

8. Ron Whitlatch, Engineering Services Director, City of Lebanon

Mr. Whitlatch wrote that the City of Lebanon recommends delaying the implementation of the permanent rules "until analytical methods become more reliable and robust, laboratory capacity is available, and total burden costs are further quantified." He opined that "the monitoring requirements for systems is complex and should be simplified by removing the cyanotoxin-producing gene analyses." His written comments detail these and other specific comments according to the proposed rule sections and subsections and are summarized below.

a. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

Fiscal and Economic Impact:

Mr. Whitlatch's written comments detail concerns that the fiscal impact to water systems for analytical costs is underestimated, particularly after the state's funding to analyze most samples ends in June 2019. He also opined that the estimated annual costs per system provided in the Statement of Need and Fiscal Impact do not provide the total cost of the rule, as it doesn't consider the total number of systems affected. He further provided information on how a detection that leads to a "do not use" advisory impacts water systems both in terms of cost to the utility or the city to have to implement an alternative way to supply customers with safe potable water, and in terms of the erosion of public confidence in the safety of the water supply when advisories are issued based upon flawed analytical methods. His written comments provide specific recommendations for the agency to consider regarding his concerns.

b. Agency Response:

See above response to Commenter (7), Agency Response (a) regarding the cost of the cyanotoxin rules.

OHA understands that costs to a water supplier during an advisory may be significant. If such an event were to occur, as we saw in summer 2018, multiple agencies would provide assistance as needed, including OHA, Office of Emergency Management, the local health department, and others. A formal incident command structure can be a useful way to ensure assistance is requested and provided as appropriate.

OAR 333-061-0520(6): Definitions

Use of the term "representative" when defining distribution sampling points in the distribution system is vague. Mr. Whitlatch requests clarification "on the number of distribution samples that are 'representative', considering cost and time burdens."

c. Agency Response:

Given that all water distribution systems are different, OHA believes it is best to allow flexibility when determining the appropriate number and locations of samples needed to lift an advisory.

OAR 333-061-0540: Cyanotoxin Monitoring

Mr. Whitlatch opined that "monitoring is not only based upon a specific calendar time-frame, but when a certain concentration is reached, such as genetic counts, additional monitoring for different analytes using different methods is required." Providing the monitoring frameworks cited in the proposed rules in his written comments, Mr. Whitlatch writes his concern that "it could become extremely confusing for a utility to know when and how to collect samples for specific analytes, especially when triggered levels are exceeded." He recommends "removal of the gene counting method from the

monitoring requirements as it becomes confusing and complex for utilities to understand when they are required to conduct monitoring."

d. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

(2)(a)(B)(iii) and (3)(a)(A)(ii)

Mr. Whitlatch provided his concern that the regulatory limit for gene counts (2500 gene counts per milliliter) is too low, and it is not clear if 48 hours or two business days is the actual deadline for sampling. He opined that the "action level is set at too low of a value and should not be used" and recommends the removal of the 48-hour requirement and simplifying the requirement to two business days.

e. Agency Response:

See above response to Commenter (1), Agency Response (a) regarding removal of qPCR requirements.

(2)(a)(C) and (3)(a)(B)

Mr. Whitlatch provided his concern that although the proposed rules have a 0.3 ug/L threshold for increased raw water monitoring, the "U.S. EPA 10-day health advisory level for cylindrospermopsin is 0.7 ug/L" and "there is no public health benefit to offset the burden of additional monitoring for levels of cylindrospermopsin below this level." He recommends using the health advisory levels and specifying microcystin as 0.3 ug/L and cylindrospermopsin as 0.7 ug/L."

f. Agency Response:

For most contaminants, when a low level is detected (less than the maximum contaminant level), additional monitoring on a more frequent basis is required to confirm the presence of the contaminant and to determine if levels fluctuate over time. Monitoring may be reduced if levels consistently are shown to be below any health-based level. In the case of total microcystins, the detection limit of the method happens to be the same as the health advisory level for vulnerable populations. Therefore, additional monitoring is required only when a health advisory level is exceeded. For cylindrospermopsin, because the lowest health advisory level is 0.7 ppb, OHA believes that 0.3 ppb is a reasonable trigger to require additional monitoring to see if concentrations change and ensure that public health is protected.

OAR 333-061-0550: Analytical Methods and Analytical Times

Citing that the proposed rule requires "three different methods of monitoring for cyanotoxins that either must be alternated or taken when a specific cyanotoxin is identified" Mr. Whitlatch provided his concern that "the ELISA method requires proficient laboratory techniques and results can vary significantly between laboratory technicians. Relying upon a method with such poor accuracy and reproducibility to issue a 'do not

drink' advisory seems ill-conceived given the gravity and consequences of a 'do no drink' advisory." He also pointed out that few laboratories can conduct the required methods and there are even fewer laboratories that are certified for the ELISA method. He recommends "delaying this Rule until analytical methods become more reliable and robust."

g. Agency Response:

The ELISA-based EPA Method 546 is considered a reliable and effective method to measure total microcystins. During method development, the degree of laboratory variability did not exceed that of other standard methods. There is no other approved method that measures total microcystins, hence cyanotoxin regulations will continue to rely on Method 546 for the time being. The DEQ lab is prepared to conduct all analysis required by this rule, assuming adequate funding is available. OHA is also prepared to accredit any labs that wish to go through the ORELAP-accreditation process for any methods required in the rule.

(1)

Citing the requirement in the proposed rules that "utilities must utilize an ORELAP-certified laboratory" Mr. Whitlatch again provided his concern that "there are few laboratories that can conduct all three analytical methods" and "there are even fewer laboratories that are ORELAP-certified for the methods" and "even fewer laboratories are willing to perform the analytical procedures on weekends, holidays or with a 24-hour turnaround time during periods of an advisory." He recommends removal of the "requirement for laboratories to be ORELAP-certified to perform the cyanotoxin analyses."

h. Agency Response:

The DEQ lab is prepared to conduct all analysis required by this rule. OHA is also prepared to accredit any labs that wish to go through the ORELAP-accreditation process for any methods required in the rule. Use of ORELAP-accredited labs is standard for all regulated contaminants and OHA does not see a compelling reason not to do so for cyanotoxins. If extenuating circumstances apply, there is a provision that allows OHA to extend the monitoring timeline required upon request.

(5)

Mr. Whitlatch requested the removal of the requirement for water suppliers to ensure that laboratories and subcontracted laboratories start analysis of samples within one business day of receipt because the responsibility for analysis to start within one business day should fall to the laboratories themselves.

i. Agency Response:

See above response to Commenter (1), Agency Response (d) regarding reporting requirements.

OAR 333-061-0560: Reporting

(1)

Mr. Whitlatch opined that notifying purchasing systems and the Authority within eight hours of when confirmation samples exceed a health advisory level is impractical. He recommends extending the deadline to at least 24 hours.

j. Agency Response:

A water system that sells water would need to issue a do-not-drink advisory in their own system within 24 hours of receipt of results, and a purchasing system would need to issue a do-not-drink advisory within 24 hours of being notified. OHA believes that it would be best to issue the advisories close to the same time to not confuse users, thus a tighter timeline for notifying purchasers is appropriate. Water suppliers that sell water should plan ahead and ensure that they have after-hours contact information.

(2)

Citing that the rule states, "the water supplier must ensure that laboratories follow the reporting requirements..." he provided his concern that "water suppliers have no authority over laboratories" and recommends that the agency "simply require laboratories follow the reporting requirements in paragraph (2)(a) – (f) of this section."

k. Agency Response:

See above response to Commenter (1), Agency Response (d) regarding reporting requirements.

OAR 333-061-0570(6): Public Notification

Mr. Whitlatch provided his concerns that the language that water suppliers must include in public notification and consumer confidence reports in section (6) "does not inform the public what they should do to protect themselves if there is truly a concern" since "routes of exposure to cyanotoxins can include skin contact, inhalation, and ingestion" and "consumers may not realize that boiling the water will not remove cyanotoxins and can increase the amount of toxin in the water by concentrating it." He recommends that the agency "consider resources from the U.S. Environmental Protection Agency and the U.S. Centers for Disease Control and Prevention to develop clearer public communication."

l. Agency Response:

See above response to Commenter (1), Agency Response (g) regarding public notification requirements.

Mr. Whitlatch's written comments are attached to this report as "Exhibit 8".

9. Cliff Leeper, Director of Public Works, City of Ontario

Mr. Leeper's written comments and the agency response are identical to those of Mr. Whitlatch summarized above.

Mr. Leeper's written comments are attached to this report as "Exhibit 9".

10. Ellen Templar, Co-Manager, Chuckel Ltd Co LLC

Ms. Templar wrote to request that small public water systems under 25 units be exempted from any additional testing. She opined that any testing in addition to the already required quarterly and annual testing for both raw water and nitrates is a financial burden on small water systems, and adding more testing creates difficulty in keeping up with all of the testing both physically and financially.

Agency Response:

See above response to Commenter (7), Agency Response (a) regarding the cost of the cyanotoxin rules.

Ms. Templar's written comments are attached to this report as "Exhibit 10".

11. Scott Impehoven, Scout Executive, Boy Scouts of America, Oregon Trail Council

Mr. Impehoven wrote that his council likes the testing but that it would be a significant burden on the council's budget if they were to have to pay for the testing.

Agency Response:

See above response to Commenter (7), Agency Response (a) regarding the cost of the cyanotoxin rules.

Mr. Impehoven's written comments are attached to this report as "Exhibit 11".

12. Jay MacPherson

Mr. MacPherson provided comments in the proposed text on four specific rules:

OAR 333-061-0530: Health Advisory Levels

Under health advisory levels, Mr. MacPherson suggested the change from "ug/L" to " μ g/L."

a. Agency Response:

OHA will change the health advisory level units to the Greek $\mu\text{g/L}$. The Uranium standard of 30 $\mu\text{g/L}$ sets this precedent and OHA strives to be consistent.

He also recommended placing a "zero" at the end of all concentration limits throughout the proposed rules to avoid confusion in numeric rounding procedures.

b. Agency Response:

EPA has established the cyanotoxin health advisory levels in the number of significant digits provided in OHA's proposed and final rule. For OHA to add a zero after this value implies a degree of precision that does not exist. While rounding to determine if a health advisory level has been exceeded can be confusing to some, the same issue exists for all regulated contaminants. Adding a zero still requires rounding to determine if an advisory level has been exceeded, depending on how many digits the lab reports for their results.

OAR 333-061-0540: Cyanotoxin Monitoring

Mr. MacPherson recommends the addition of language throughout this rule to provide flexibility in the coverage of newly established cyanotoxin health advisory levels as they occur.

c. Agency Response:

If EPA revises or creates new health advisory levels for cyanotoxins, Oregon rules would likely be revised through a formal rule-making process.

OAR 333-061-0550: Analytical Methods and Analytical Times

Mr. MacPherson provided specific language change to section (5) of this rule.

d. Agency Response:

The commenter is proposing alternate language that meets the same intent as the language in the proposed rules. OHA believes the existing language is clear and concise.

OAR 333-061-0560: Reporting

(2)

Regarding the requirement that the water supplier must ensure that laboratories follow the reporting requirements of this section, Mr. MacPherson questioned "what is the consequence if a lab fails to comply?"

e. Agency Response:

If a lab does not meet the reporting requirements of the rule, the water supplier would not be in compliance with that section of the rule. OHA believes it is reasonable to suggest that water suppliers only work with labs that are capable of meeting the

required analytical and reporting times. The DEQ lab is capable of meeting these timelines, assuming adequate funding is available.

(2)(a) and (b)

Mr. MacPherson suggested the change of the word "begins" to "is complete" in reference to the requirement that laboratories are required to report sample results to the Authority and the water supplier.

f. Agency Response:

Changes suggested by the commenter do not meet the intent of the rule. Allowable analysis times are longer according to the method, so OHA limited the time for a lab to analyze and report the results of the sample due to the health effects associated with a high result. If the only reporting time was regulated after analysis, high results may not be received soon enough to take protective actions for public health.

Mr. MacPherson's written comments are attached to this report as "Exhibit 12".