Division of Drinking and Ground Waters Response to Comments

Draft New Chapter 3745-90 and Amendments to 3745-89 of the Administrative Code

3745-90-01, Harmful algal blooms – definitions
3745-90-02, Harmful algal blooms – applicability and action levels
3745-90-03, Harmful algal blooms – monitoring
3745-90-04, Harmful algal blooms – analytical methods and reporting
3745-90-05, Harmful algal blooms – treatment techniques
3745-90-06, Harmful algal blooms – Tier 1 public notification and consumer confidence reports
3745-90-07, Harmful algal blooms – recordkeeping
3745-89-01, Laboratory certification definitions
3745-89-02, Analyses requiring laboratory certification
3745-89-03, Procedure for laboratory certification
3745-89-04, Renewal of laboratory certification
3745-89-05, Maintenance of a laboratory certification
3745-89-06, Director's actions for laboratory certification
3745-89-08, Reporting of analytical results

Agency Contact for this Package

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Ohio EPA issued public notice and requested interested party comments for the period of Sept. 22, 2015 to Oct. 23, 2015 on draft rules in the Ohio Administrative Code (OAC). This document summarizes the comments and questions received during the interested party public comment period.

Ohio EPA reviewed and considered all comments received during the interested party comment period. By law, Ohio EPA has authority to consider specific issues related to protection of the environment and public health.

In an effort to help you review this document, the questions are grouped by topic and organized in a consistent format. The name of the commenter follows the comment in parentheses.

General Comments

Comment 1: **The following are comments on the costs of the rules:**
Cost-benefit justification for the proposed regulations does not appear to have been fully evaluated or demonstrated based on the excessive and conservative

monitoring frequencies, as well as the reliability of the testing method required to be used in the proposed rules.

"The monitoring, data collection and testing required by the regulations appears more of a research study rather than implementation of reliable regulatory oversight to the probability of occurrence to a specific public health issue. Ohio residents will pay for excessive monitoring and testing for cogenes which have not been demonstrated to have health impacts but will be measured and reported."

"Maybe more important than the direct costs of complying with the proposed monitoring program is the indirect cost and cost of loss public confidence resulting from false positive monitoring results. The costs of loss confidence in the safety of public water system may be borne by the regulatory agency promulgating regulations not based on scientific evidence based information. In all cases, the full direct and indirect costs will be borne by the residents of Ohio."

"While the Ohio EPA proposed regulation requires the analysis of microcystins by what is supposed to be a relatively inexpensive method (compared with some UCMR methods), the costs add up quickly. Even with an estimated cost of $100 per sample for ELISA testing, this comes to $10,400 for each surface water plant. Quotes we have received from commercial laboratories have been in the range of $70-$150/sample for ELISA-ADDA testing of microcystins." (Thomas T. Schwing, Aqua Ohio, Inc.)

"At minimum the cost associated with sample collection, shipping, and analysis of these weekly samples for one year is estimated to be in the range of $25,000 per surface water treatment plant. With 125 surface water treatment plants in Ohio, the statewide cost for this sampling and data collection effort may exceed $3 million. While we understand OEPA's desire for additional data collection, it is imperative that OEPA make funds available, especially for small and mid-sized systems, to minimize this cost burden for cash strapped drinking water utilities. In addition, weekly monitoring imposes significant staffing burdens on small and medium sized utilities where staff perform multiple functions at water treatment plants."

"Screening and monitoring should be reduced to a less burdensome frequency, particularly in winter months. In order to reduce the substantial cost of meeting the OEPA's 52 week sampling protocol, Ohio EPA should reduce the screening and monitoring frequency to a monthly schedule during at least part of the year. Ohio EPA should review the monitoring frequency requirements in the proposed rule under all action level scenarios and require only the minimum number of sampling events necessary to protect public health." (Tyler S. Converse, Ohio Water Utility Council of the Ohio Section AWWA)

"The proposed rules require at a minimum weekly, year-round screening and monitoring sampling that will impose significant cost and staffing burdens, especially during the off seasons. Off season testing requirements of weekly

sampling should be eliminated from the drafted rules, as data shows that the toxins that are in question are specific to warm weather, and that testing in the off season would be a large financial burden with very little gain for the plant or the public." (Edward A. Moore, City of Toledo)

It is the water system's experience that algae blooms are not an issue during the months of November through February. The cost of testing weekly will eventually be passed on to the consumer and it should be considered whether the public's money is being spent wisely and in a responsible way, considering everything when making new rules. (Wayne Moore, Village of Blanchester)

"We believe consideration should be given for removing or reducing sampling requirements for months not typically associated with HABs. Perhaps one sample per month for November through May would be more reasonable for budgets but still provide reasonable assurance of compliance." (Glenn Marzluf, Del-Co Water Company, Inc.)

The cost to the public to implement these regulations could be immense. The public water system has the intention of continuing to monitor during from July through October despite what happens with the regulations. The cost to this system is $500 per week and if increased to the 52-week requirement, would mean an extra expense of $17,000 in 2016. For smaller public water systems, this cost could amount to an additional $25,000 per year. Additionally, the bigger expense to systems is the cost to issue a "Do not drink" advisory. The estimated impact to Toledo for issuing this advisory in 2014 was $2.2 to $2.5 million. "The economic impact for the damaged reputation to water utilities extends to tourism, industry and the reputation of the state, in general." (Todd A. Danielson, Avon Lake Regional Water)

"Estimates of the economic impacts of the do not drink advisory are as high as $30,000,000.00 (see http://osbcouncil.com/small-businesses-discuss-the-money-lost-during-the-water-crisis). The University of Toledo has completed a study on the economic impact to the area; however, the study is not yet ready to be released. We will share the study with you when it becomes available." (Edward A. Moore, City of Toledo)

The economic impact estimates of the 2014 Toledo 'do not drink' advisory was millions of dollars. "The longer term economic impact is the loss in public confidence in the safety of Toledo water, resulting in lost revenues to the utility. We request the Agency consider immediate and long-term economic impacts as part of the detailed economic impact analysis." (Alex Margevicius, City of Cleveland)

The City of Steubenville and other water plants "just don't have that kind of money" to monitor weekly "in our budgets. We our located on the Ohio River. Our neighboring plants are 5 miles apart. I think it is a complete waste to have all of us to test the same water. It would make more sense to have ORSANCO do the testing at each lock and dam or at selected volunteer plants that are spaced

out further. If a HAB is detected then maybe do more testing in the area of the HAB."

"Purchasing the equipment is not really an option for us either. The $30,000 won't even cover all the equipment cost and then there is the reagent cost as well. Our lab is too small. You pretty much have to be doing your own microbiological in house already to have a complete separate area and glassware for the testing. We do not do them in house and send them out. Most plants do. I also heard that it takes 4 to 6 hours to run a set of samples. Who has that kind of time. Most plants are already understaffed. We are." (Joe Bottegal, City of Steubenville)

Will there be any funding available to help smaller water systems that do not have the money budgeted for the added expenses? The increased monitoring (three days per week) based on detections of microcystins above 5 µg/L in the raw water may be a cost concern for smaller systems at this threshold. (Brad Brown, Shelby Water Plant; Alice Godsey, City of Perrysburg)

Ohio EPA should provide assistance to systems for the costs associated with the testing as outlined in the draft rules because the costs could become significant and especially for increased sampling. Sampling in both raw and tap water in colder months seems to result in low or non-existent algal toxin occurrence. "If there is information that warrants this extensive data even during times of extremely low chances of occurrences, maybe large utilities with resources would be willing to provide data during these monitoring periods. The costs for this testing is expected to exceed $12,000 just for the routine sampling that is proposed in the draft plan. Once a utility has a detection, this sampling will become much more expensive very quickly. This cost is significant to a small utility's budget… Many surface water utilities took advantage of sondes and flourometers and will also incur man hours and O & M costs associated with those instruments as well as the toxin testing the OEPA is requiring."

"For utilities who will not be performing these tests in their own laboratory due to lack of staffing and equipment, and if analysis of samples are required within 24 hours of collecting due to a detection; this again could be quite costly especially if it falls on a weekend or a holiday. I realize that this may be necessary in the instance of a detection but with no assistance for analysis or cost of analysis it will be financially burdensome in addition to the routine testing being required every week for 52 weeks on both raw and tap samples."

"This past year, the OEPA and Ohio water utilities joined forces to monitor and be proactive in sampling and learning more about toxic algal blooms. Most surface water treatment plants have PAC or even GAC to combat algae in their source water. Please let water utilities manage their plant and treatment and spend their limited resources on removing organics and algae and improving treatment rather than spend the money on weekly sampling with yet second and third waves of testing for additional toxins." (Sandra O. Vozar, The Village of Fairport Harbor and City of Berea)

The screening and monitoring analysis as proposed in the rule will approximately double Westerville's laboratory operational budget, as well as put a significant burden on their laboratory analysts' time capabilities. "Utilities the size of Westerville and smaller, that generally have a smaller and less specialized staff, will struggle freeing our staff to comply with this time consuming weekly analyses. We believe that the proposed monitoring requirements can be reduced and still be protective of public health." (Richard C. Lorenz, City of Westerville)

"Requiring every surface water system in the state to analyze weekly for a year is fiscally irresponsible, especially during the off season. Off season testing requirements of weekly sampling should be eliminated from the draft rules altogether. There are large quantities of data that shows the toxins in question are warm weather specific and testing for them in the off season would be huge expense for absolutely no gain. Spending $250 per week to get a zero result is not only expensive, but wasteful. The City's cost to run and analyze both the Raw and Finished water weekly for a year will be a minimum of $13,000 and easily exceed $17,000 if raw water levels are greater than 5 ppb during summer months." (Doug Wagner, City of Oregon)

"In the October 2015 edition of the AWWA's *Journal*, the AWWA association pointed out a number of problems with the regulation of cyanotoxins, along with several practical steps to take to address such problems. Importantly, this AWWA publication also identifies the substantial financial burden on a community of between $103 to $220 per person per day when there is a "do not drink" order. Considering that Akron has over 280,000 customers, a "do not drink" order will have a devastating financial impact on Akron's community. This financial burden was not considered by the Ohio EPA as part of the Proposed Rules. Such a financial burden must be included in the evaluation as part of the Proposed Rules, especially since the Proposed Rules include action levels that are not based upon sufficient scientific evidence." (John O. Moore, City of Akron)

Following the rules, which are based on health advisory levels with an overly – conservative approach, may lead to communities incurring substantial direct and indirect costs as a result of issuing a 'do not drink' advisory when it is not necessary. "Based on FEMA (2010, Hazard Mitigation Assistance Unified Guidance) estimates, this would result in a cost impact of over 100 million dollars per day for the Cincinnati area." (Jeff Swertfeger, Greater Cincinnati Water Works)

"The PWS's don't have the money to conduct out of season tests just to provide the Ohio EPA with base data. If Ohio EPA believes that it is really necessary to secure year round microcystin data, then use the State of Ohio's money to pay for monitoring the State's waters."

"It should also be noted that the PWS's on Lake Erie have spent millions of dollars to treat the algae in Lake Erie over the past few years; while many systems are planning on spending millions more just to address the issues with

the poor lake water quality. All of these additional costs have been paid for by local water customers." (Ron Wetzel, Ottawa County)

"Our preliminary estimates for qPCR shipping materials, labor costs, and sample materials will be approximately $9,500 per year. Weekly analysis with the ELISA-ADDA equipment will be approximately $46,200 per year, assuming one raw and finished water sample per week from each plant. The employee time is significant because it takes away from other critical laboratory needs or overtime costs will be incurred to maintain other laboratory duties. As part this public commenting process, we request Ohio EPA provide an adequate, detailed economic analysis summarizing the impact of these HAB rules on water systems, including small systems." (Alex Margevicius, City of Cleveland)

"We are a large system and typically budget $30,000 +/- in outside, independent laboratory services. For a system without history of algal issues, doubling our sampling costs is severe. Our customer base may be large enough to absorb the substantial increase, however, the majority of systems serving a population <10,000 lack the time, resources and specialized staff to perform the required testing and will therefore be obligated to have samples analyzed by an independent laboratory. This cost will be substantial for such systems. Using Ohio EPA's estimates for the ELISA analysis and the Cyanobacteria Screening, the total cost for one surface water treatment plant ranges between $8,840 and $22,880 for one year of analysis. This estimate does not include costs associated with additional monitoring which may be triggered by a microcystin detection." How are smaller systems expected to manage with such an increase in cost for water quality monitoring and analysis?"

"Using Ohio EPA's estimates for the ELISA analysis and the Cyanobacteria Screening, the total cost per year for systems with two surface water sources range between $17,680 and $45,760; and for systems with three surface water sources, total costs range between $26,520 and $68,640. This estimate does not include costs associated with any additional monitoring which may be triggered by a microcystin detection. How are systems with multiple surface water sources expected to incur such an increase in cost for water quality monitoring and analysis? (Glenn Marzluf, Del-Co Water Company, Inc.)

"We urge the Agency to revise the rules to require monitoring only during the periods of significant HAB activity." (Philip Van Atta, City of Dayton)

Response 1: Ohio EPA has considered the costs of these rules on public water systems, and on the public which could see costs passed down through increased user fees. To provide some assistance and relief for these costs, Ohio EPA has made $1 million dollars in grants available to public water systems to establish their own analytical capabilities, and continues to provide funding assistance through zero- to low-interest loans for infrastructure improvements.

Ohio EPA believes the costs of these rules are justified and necessary to successfully achieve the directives established in Senate Bill 1 (R.C. 3745.50) and address public expectations that public water systems routinely monitor and

treat for cyanotoxins. Ohio EPA takes the issue of loss of public confidence seriously, and believes that anything short of rules which clearly require all surface water systems to routinely monitor and reliably treat for cyanotoxins would result in a greater loss of public confidence. This is apparent in some comments received which indicate the draft rules are not stringent enough. The treatment techniques were included in the rules in an attempt to ensure public notification would *not* be necessary, because water systems are actively addressing HAB issues through source water protection, reservoir management, avoidance strategies and demonstrated treatment.

Ohio EPA continues to believe that year-round sampling is necessary for public health protection – not for research purposes – because microcystins have been detected, sometimes in high concentrations, in the limited sampling that has been conducted during the "off season". While microcystins are most often found during the warmer months, they have been detected in source waters all year round. The majority of sampling so far has focused on the warmer months, so testing results could be an underrepresentation of occurrence in the "off season". In addition, only about half of all surface water systems in Ohio have been sampled for microcystins. HABs are not always visually apparent, and can be present and produce cyanotoxins in winter, including under ice. The only way to know if microcystins are present is to sample for them.

While Ohio EPA does not consider it appropriate to completely eliminate all sampling requirements during the "off-season", the overall number of required samples is half of what was proposed in the draft rules. Ohio EPA has reduced the frequency of the initial routine monitoring requirements during the lower-risk period of November to April, which will alleviate some of the cost burden. The rule also allows for further reductions in monitoring if a reduction is supported by the monitoring data. It remains Ohio EPA's intent to wait until a year of monitoring is completed to consider revised monitoring schedules; however, the one-year limitation has been removed from the rule to allow flexibility for Ohio EPA to act sooner should it become appropriate.

Ohio EPA has also reduced the frequency of cyanobacteria screening samples from weekly to once every two weeks.

Comment 2: **The following are general comments on the science behind these rules:**
"Ohio EPA's microcystin action levels may be broader and more stringent than what is required to protect public health. The Ohio EPA action levels are broader and significantly more stringent than World Health Organization guidelines and the guidelines in place in Canada and Australia. Moreover, Ohio EPA's action levels are based upon the presence of total microcystins, not microcystin-LR, the specific toxin upon which US EPA and international guidelines and the relevant scientific research are based. There should be more flexibility if it has been less than 10 days since the last non-detect sample. It is every treatment plant's mission to protect the public health. Ohio EPA should reconsider the action levels in the proposed rules and revise these levels to conform to science-based standards that are necessary to protect public

health." (Tyler S. Converse, Ohio Water Utility Council of the Ohio Section AWWA; Edward A. Moore, City of Toledo)

"There appears to be insufficient science to establish the Action Levels and requirements once those levels are reached." The levels are based on a U.S.EPA document with recommendations for PWSs to manage cyanotoxins in drinking water and states, *Health Advisories values are an estimate of the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for a period of exposure.* "Therefore, exposure to the 10-day Health Advisory level is not expected to cause any problems." The companion U.S. EPA document to U.S. EPA recommendations, Drinking Water Health Advisory for Microcystins, "indicates that there is limited data demonstrating the absorption of microcystins in the intestinal tract of humans and animals. The document further states that a rat study was the critical study determining a reference dose and those results had a safety factor of 1,000 applied to them in order to determine the Health Advisory Level. This data seems far less developed than the typical process for establishing Maximum Contaminant Levels and is establishing levels of conservatism far beyond normal." (Todd A. Danielson, Avon Lake Regional Water; Doug Wagner, City of Oregon)

"The current advisory for finished water is based on the U.S. EPA guidance for a 10 day exposure which was derived from a study based on a 28 day exposure with no adverse effects. The prior advisory of 1.0 µg/L was based on the WHO lifetime exposure. Without any additional research to support this change, why are we going from a 1.0 µg/L lifetime exposure down to 0.3/1.6 µg/L – 28 day exposure and next to 0.3/1.6 µg/L – 10 day exposure and now to not mention whatsoever of the 10 day exposure in the draft rule? This only serves to induce panic and reduce the public perception of their water suppliers." (Doug Wagner, City of Oregon)

"Ohio EPA is attempting to compress a significant regulatory effort into a very short period of time." Ohio EPA's proposed rules have not gone through the scrutiny US EPA typically goes through with rule development. "Most significantly, in our opinion, the epidemiology component is categorically deficient. Analytical methods are being developed on the fly fast than can be properly evaluated, critiqued, and improved upon to the level expected in the drinking water industry."

"On what legal basis can Ohio EPA enforce a federal Health Advisory level as something more than guidance when industry-accepted epidemiology studies have not been conducted?" (Alex Margevicius, City of Cleveland)

"Ohio EPA appears to ignore the information collected to date by the USEPA on health exposure to microcystin toxins. What studies have Ohio EPA conducted or is relying on to support the efficacy of the proposed regulations?

"There is by no means consensus in the scientific community on the severity of the adverse health effects at the concentrations proposed in Ohio EPA's Action

Levels. The USEPA health advisories were developed for a 10-day exposure, yet the proposed Ohio EPA regulation requires action well before a 10-day period has passed. This makes for a confusing situation when trying to make sense of the severity of exposure to water at a given concentration of cyanotoxin. In addition, the establishment of a different Action Levels based on ages of residents may lead to confusion for the consumer."

"In essence, the proposed rule is requiring that all surface water sources in Ohio conduct research studies to assess the occurrence of cyanotoxins in raw and treated waters. When done at the federal level (UCMR), it is common for quarterly testing of surface water supplies to be tested for unregulated contaminants – typically only at the treated water entry points. This is done for the purpose of generating occurrence data nation-wide so that USEPA can have a better scientific foundation on which to write a drinking water regulation (or to determine if occurrence warrants regulation)."

"The use of none standardized test methods (qPCR); monitoring frequencies during seasonal times when there is low probability of microcystin presence; monitoring for microcystin in finished water when it has not been demonstrated to be present in raw water; and the use of the ELISA-ADDA method which has a positive bias all suggest that the proposed regulation focuses more on data collection rather than public health protection demonstrated by rigorous scientific data." Also, while "the proposed standards are being called Action Levels, they may be difficult to distinguish from Maximum Contaminant Levels (MCLs) in their level of enforcement. The basis of the USEPA health advisories has not undergone the same level of scientific scrutiny as is typically required for a MCL." (Thomas T. Schwing, Aqua Ohio, Inc.)

"…the Proposed rules are premature and are not based upon sufficient scientific evidence. Importantly, microcystins in drinking water are not currently regulated with a standards regulation or guideline under the federal Safe Drinking Water Act. In addition, total microcystins are not listed on U.S. EPA's Contaminate Candidate Lists for possible future regulation." U.S. EPA's health advisory document is what the proposed rules action levels are based upon, but these are based upon very limited research and data. "As stated by U.S. EPA, Health Advisories *serve as informal technical guidance… and are not legally enforceable standards and are subject to change as new information becomes available.* Thus, in the Proposed Rules, Ohio EPA is imposing action levels based upon an informal technical guidance that is not legally enforceable and is subject to change as new information becomes available."

"U.S. EPA's latest published list of all standards and health advisories is from 2012. There are over 200 chemicals on the 2012 list, yet 116 of these chemicals did not have a regulatory standard, but rather, only had a health advisory. Therefore, there are numerous chemicals that are subject to a U.S. EPA health advisory, but are not subject to regulation under the federal Safe Drinking Water Act or subject to regulation by Ohio EPA."

"The establishment of regulatory standards under the Safe Drinking Water Act, including monitoring, reporting and laboratory certification standards, are based upon a thorough, well-defined scientific process. The regulatory process followed by U.S. EPA involves developing data that is gathered and evaluated in accordance with scientific protocols. Moreover, recommendations for monitoring, treatment, testing, reporting, health standards, and notifying the public will change as part of this ongoing regulatory process." Akron recommends Ohio EPA "delay its rule making effort until U.S. EPA implements the forgoing regulatory process." (John O. Moore, City of Akron)

"The AWWA notes that Health Advisories are traditionally used to describe potential health issues and are used to promote discussion within the water sector and to direct future regulatory agendas. Here, U.S. EPA is recommending that Health Advisories be used as the basis to trigger 'do not drink, do not boil' advisories for microcystin. AWWA states that U.S. EPA has failed to provide justification for such action and, further, that there is no scientific, regulatory, or other appropriate precedent to recommend such action based on a Health Advisory (AWWA. July 2, 2015. *Economically Significant Guidance Request for Cyanotoxins Recommendations.*) What is Ohio EPA's response to this assertion?" (Glenn Marzluf, Del-Co Water Company, Inc.)

"The WHO Guidelines for Drinking Water Quality states, *Chemical analysis of cyanotoxins is not the preferred focus of routine monitoring. The preferred approach is monitoring of source water for evidence of blooms, or bloom-forming potential, and increased vigilance where such events occur. Analysis of cyanotoxins requires time, equipment and expertise, and quantitative analysis of some cyanotoxins is hampered by the lack of analytical standards… Chemical analysis of cyanotoxins is useful for assessing the efficacy of treatment and preventive strategies…* " (Philip Van Atta, City of Dayton)

Furthermore, this study and information has been available thru the WHO since 1999. Why is the OEPA suddenly and more swiftly concerned with this than the US EPA?" (Sandra O. Vozar, The Village of Fairport Harbor)

"Also, per the Ohio EPA Total Microcystins ADDA by ELISA Analytical Methodology, test interferences cause by matrix effects (Item 4 in that document) are as yet unidentified. That document also identifies a Low Range Calibration Range Check for the ELISA test in the range of 0.30 µg/L to 0.50 µg/L with an acceptable range of ±40%. As interferences are unknown, and with such a large error range in the lower detection range, to mandate additional sampling and corrective actions at the stated MDL for the test, the lower of the two stated action levels, is problematic. An increase in the action level to correspond to the inherent error range of the test in question would be imminently justifiable." (Aaron McCoy, Campbell Soup Supply Co.)

According to the draft rules, "a single result that exceeds the 10-day health advisory level of 0.3 µg/L for infants is presented as justification to implement costly treatment modifications, additional monitoring, and source water protection. This single result would be based on a laboratory method that,

according to USEPA ETV 2010, has a potential error of up to 40% for samples containing 0.5 µg/L microcystin-LR and even greater error for congeners." (Philip Van Atta, City of Dayton)

Response 2: Ohio EPA has based the microcystins action level on the "Drinking Water Health Advisory for the Cyanobacterial Microcystins Toxins" issued by U.S. EPA in June 2015. This document underwent two rounds of expert peer review. As with many regulated contaminants, Ohio EPA recognizes there are some toxicological data gaps, but this is currently the best available science regarding health effects of microcystins. The inclusion of safety factors in the development of U.S. EPA's health advisories is consistent with standard practice, including in the establishment of maximum contaminant levels (MCLs). Other states use U.S. EPA health advisory levels as enforceable limits.

The U.S. EPA health advisory is explicitly for total microcystins, using microcystin-LR as a surrogate since it is the congener for which the majority of toxicological data is available. Thus, selecting an analytical method capable of measuring total microcystins is appropriate. A study in 2014 determined that there were 16 different microcystin congeners present in 11 Ohio source waters. Given that occurrence, limiting Ohio's action level to Microcystin-LR only would not be protective. Aside from ELISA, the other analytical methods included in U.S. EPA's health advisories are currently limited in their ability to measure all congeners, and therefore underreport total microcystins. For example, the 2014 study demonstrated that 90% of Ohio source water samples contained microcystin congeners that were not detectable by U.S. EPA Method 544.

Since the specific toxicity of all known and unknown congeners (and methods for detecting each and every one) is not available, Ohio EPA considers this to be a protective approach similar to that used for *E. coli*. *E. coli* also has several strains of varying pathogenicity (most notably O157), but U.S. EPA and Ohio EPA regulate them as a group of organisms that have the potential for harm. To regulate them as individual strains would be inefficient and expensive, and could expose the public to dangerous strains that have not yet been identified or studied. Given the numbers of microcystin congeners, it is unlikely that toxicological studies will ever be conducted for each individual congener to support a health advisory for each. However, data show that the presence of the ADDA moiety, which is present in all microcystins congeners, is key to microcystin's toxicity.

Ohio EPA has carefully reviewed all of the analytical methodologies currently available, including performing a comparative analysis and an evaluation of potential interferences. Ohio EPA considers the ELISA-ADDA method as suitable for quantitative analysis, and does not consider the ELISA-ADDA method to be solely useful for screening purposes. Most U.S. EPA approved organic analytical methods for drinking water allow for acceptance limits for quality control standards of ±50% at or near the reporting limit and acceptance limits of ±30% near the midrange of the analytical method. Additionally, U.S. EPA method 544 for detection of 6 microcystin congeners allows for acceptance limits for quality

control standards of ±50% at or near the reporting limit and acceptance limits of ±40% near the midrange. After completing accuracy and precision studies, Ohio EPA has tightened accuracy and precision acceptance limits for quality control standards of the ELISA-ADDA method to ±40% (near reporting limit) and ±25% (midrange). Ohio has not seen any studies that support the statements that ELISA-ADDA over-reports or has interference issues. If available, please provide this information.

Based on the results of Ohio EPA's method comparison study, HPLC-PDA was prone to both false positives and false negatives and LC-MS/MS individual variant analysis (such as U.S. EPA method 544) under-reported total microcystins. These methods are also more expensive, take longer, and there is less laboratory capacity as compared to the ELISA-ADDA method.

It should be noted that the rules call for multiple samples prior to a Tier 1 public notice, further eliminating concerns of taking actions when there are questions on specific analytical results.

Alternative methods continue to be evaluated and validated and may be acceptable for use in the future.

While the qPCR method is still being refined, Ohio EPA does not anticipate using it in a regulatory fashion but rather as a screening tool that prompts further testing for cyanotoxins via another method. This screening is currently being conducted via algal identification. qPCR, which identifies and quantifies whether the genes responsible for production of cyanotoxins are present, has specific advantages over algal identification. Specifically, the test is fast, cost effective, specific and uses certified reference material.

As noted in the response to Comment 1, Ohio EPA considers routine monitoring to be essential as HABs are not always visually apparent and an approach based on visual observations therefore has limitations.

Comment 3: **The following are general comments on issuing public notification:**
"Under the proposed rules, Ohio Section member utilities and the communities they serve will be required to accept the significant disruptions and social costs resulting from Tier I public notification and there may be no significant threat to public health present. Ohio EPA should reconsider the action levels in the proposed rules and revise these levels to conform to science-based standards that are necessary to protect public health. Further consideration should also be given to the ability of a public water system to utilize the full 10-day health advisory window to reduce cyanotoxin levels, prior to requiring public notification." (Tyler S. Converse, Ohio Water Utility Council of the Ohio Section AWWA)

The requirement to issue public notice on the second or third day when a microcystin is detected in the finished water appears to be extreme and has the potential to significantly impact the cost of the regulation. "With a safety factor

of 1,000 for a 10-day exposure that is not anticipated to cause any problems, we question why notification two to three days into an event is necessary. We understand that part of this relates to when the last non-detectable sample was collected. However, if samples are collected multiple times per week, and it can undoubtedly be stated that an event is only two to three days old, notification this early seems quite premature when a system is actively optimizing treatment levels and implement other measures to assure the 10-day Action Level is not achieved."

The draft notice does not include language stating that the required action level is based upon a 10-day exposure and as currently written, could cause more concern than necessary because people think in terms of "below a certain value, they are safe; above a certain value, they are in trouble. The Action Level relates to being exposed to a certain value for at least 10 days. It also assumes they are consuming a certain amount of water. It is highly likely that consumers will receive the notification well before ever accumulating the reference dose of microcystin."

"Please do not implement a regulation that requires such quick public notification based upon what appears to be large safety factors based upon limited scientific information." (Todd A. Danielson, Avon Lake Regional Water; Doug Wagner, City of Oregon)

"The standard health advisory language needs significant revision to state the fact that the action levels are based on a 10-day exposure. Again creating undue panic in the community is not the mutual interest of anyone." (Jeff Swertfeger, Greater Cincinnati Water Works)

"The health advisory levels are for 10-day exposure for quantities of toxin greater than the action level. Tier 1 notices are reserved for acute risk to public health. Therefore, issuance of a Tier I notice, required by the Draft Rule, conveys to the public that ingestion of any amount of water is immediately dangerous to health when clearly that is not the case. Test results are based on methods which are not fully reliable. Thus, inaccurate results could trigger Tier I public notifications that may create unnecessary panic, economic hardship, and loss of public confidence in public drinking water." (Philip Van Atta, City of Dayton)

The proposed public notification requirements "appear extreme and may lead to public confusion. The PN requirements are not consistent with USEPA's current Health Advisory recommendations relating to 10 day exposure; uses Ohio EPA's format for public water system's Notice of Violation (NOV) format rather than Health Advisory notification; has the potential to significantly impact the cost of this regulation through direct and indirect costs; and may generate confusion among Ohio residents and water consumers by the nature of the notification."

"Assuming microcystin toxin is identified in the finished water, the proposed regulations' short timeline for PN may not allow the WTP's response to treatment changes to remove the toxin causing undo public alarm. This may

cause a needless reduction in the public's confidence in their public water system."

"What studies has Ohio EPA conducted or relied on to establish the need for PN in the timeframe specified in the proposed regulations to protect public health?" (Thomas T. Schwing, Aqua Ohio, Inc.)

The proposed rules involve public information requirements that are far more stringent than the USEPA Health Advisory guidance. "HAB messaging is essentially public notification. Targeting 'at-risk populations' is essentially targeting the entire population. Ohio EPA should strictly adhere to USEPA's guidance regarding the 10-day Health Advisory level. Messaging at any point before the 10-day milestone is telling the public this is an acute toxin scenario. USEPA did not have the epidemiological support to make this statement, and Ohio EPA should not either. Cleveland Water sees no purpose in premature messaging other than to confuse customers about the safety of their water. In the absence of epidemiological studies based on total microcystin, we believe Ohio EPA is irreversibly damaging the confidence of the public in their water supply with no scientific basis for doing so." (Alex Margevicius, City of Cleveland)

Response 3: Ohio EPA believes it is essential to be open and transparent with the public regarding detections of cyanotoxin in finished drinking water above the action level.

The action level is based on U.S. EPA's 10-day health advisory level. This is the level *at and below* which adverse effects are not expected over a 10-day exposure. This cannot be interpreted to mean that individuals can tolerate any amount above that level for 10 days. The available science of toxicology drove the 10 day advisory level. U.S. EPA was unable to establish a shorter term health advisory level due to lack of toxicological studies. U.S. EPA has described the 10-day health advisory levels as "not to exceed" numbers with a cushion. This provides PWSs some limited time to take actions to limit exposures.

Ohio EPA understands the desire to adjust treatment with the hope to avoid having to issue an advisory which will undermine public confidence. As such, Ohio EPA has allowed some limited time to adjust treatment before an advisory is required, where conditions are appropriate. For example, there were instances in 2015 where PWSs had an initial exceedance in finished water but were able to adjust treatment and avoid issuing an advisory. In addition, Ohio EPA will require distribution sampling that can be used to limit the extent of an advisory. However, extending the time period to 10 consecutive days above the action level before notifying the public is not an appropriate interpretation of the 10-day health advisory level. In addition, issuing an advisory after many days have passed where people were exposed to cyanotoxins above the action level (while treatment adjustments were attempted) will be unacceptable to the public and undermine confidence in the water system even more.

The two-tiered approach allows us to prevent, as much as possible, extending the advisory to everyone while being protective of sensitive populations. People may make personal decisions about their own water use when an advisory is issued. Messaging will be a key component of any advisory.

The action levels in OAC rule 3745-90-02 were revised to include a reference to U.S. EPA's Health Advisory guidance and a comment was added referencing the 10-day exposure.

Comment 4: **The following are comments on addressing source water protection and nutrient pollution:**

"The HAB Reporting Rules will help detect toxins in the drinking water supply but they do little to address the root source of the problem: nutrient pollution. Excessive nutrients clearly impact the health of our waterways by fueling algal growth. The establishment of cyanotoxin general plans for treatment plants may help specific watersheds, but the Ohio EPA needs to enforce limits on nutrient discharges as part of the nutrient reduction strategy."

"While general plans that address source pollution may be within the purview of the public water systems located within isolated watersheds, several public water systems exist within Ohio which draw water from shared sources, including sources as large as the Ohio River and Lake Erie, which transcend community boundaries. While a local jurisdictional approach is to be applauded, source water protection for such water may require a more comprehensive and inclusive approach than the originated at the local PWS level. In other words, the responsibility for nutrient reduction should not lie solely on the PWS's, but should be shared among all communities sharing a surface water source to a degree commensurate with relative contribution, along with state-level enforcement agencies." (Jen Miller, Ohio Chapter Sierra Club)

"In addition to developing sound rules for HAB occurrences, we encourage the agency to also address high nutrient levels in surface water that create algal blooms and cyanotoxins. HABs are caused by conditions (agriculture and wastewater discharges) that are outside the control of public water systems. What will Ohio EPA's role be for source water protection that is outside the political boundaries of a public water utility?" (Philip Van Atta, City of Dayton)

"Why would the Ohio EPA mandate that PWS's conduct microcystin all year long? If the Ohio EPA wants to know what is going on throughout the States surface waters during the colder months of the year, the State should go out and perform its own tests in the areas that they are concerned with (like at the mouth of the Maumee or Sandusky rivers where unregulated nonpoint source pollutants are carried out into Lake Erie, or where algae scum forms and the wind blows that scum into the shoreline or backwater areas)."

"What would happen if the agriculture community was regulated to test their drain tile outlets for phosphorous or nitrogen once per week all year long (to confirm levels at the root cause of the problem)?"

"Ohio legislators and the state really need to look at the cause and effect relationship of this problem and target the right entities… up until 4 years ago, the Ohio EPA was utilizing public revenues available through the Division of Environmental and Financial Assistance to assist in the financing of agricultural drain tile installations… public revenues were being spent on agricultural drain tile project that have directly contributed to the microcystin problem we are experiencing." (Ron Wetzel, Ottawa County)

Response 4: Ohio EPA agrees that source water protection and nutrient management are critical to address the underlying causes of HABs. More information about nutrient management initiatives in Ohio can be found at http://epa.ohio.gov/dsw/wqs/NutrientReduction.aspx. Concurrent with these initiatives, Ohio must acknowledge and mitigate the current public health risks that are caused by HABs. As noted in the response to Comment 1, Ohio EPA continues to believe year-round monitoring is necessary but has reduced the monitoring frequency during the November to April time period.

Comment 5: **The following are comments about including other HAB toxins/contaminants in the draft rules:**

"We have concern for other toxins or emerging contaminants that may be present in the future and subsequent testing for those that may be required such as saxatoxin and anatoxin. Are these toxins possible or probable in Lake Erie as well? And if so, why wouldn't monitoring or testing be required at this time for those toxins which are also believed to be just as dangerous?"

Will all utilities need to address the other toxins in the future? "You state that this data will be used to determine if future testing will be required for other toxins. So are you unsure where those other toxins are dangerous at this time? Specifically, Berea's Coe Lake water source, Barberton, and a few other utilities have had saxatoxin detection in their waters but not microcystin. Why would these utilities not sample for what is known to be a possible problem and not for what is most likely not there (yet). Wouldn't consumers be misled thinking we are doing algal toxin testing and reporting negative results when a real threat could be lurking but because Toledo, Grand Lake St. Mary's, and other utilities had 'big' problems with microcystin and so that is what all surface water sources must sample for." (Sandra O. Vozar, The Village of Fairport Harbor and City of Berea)

The Ohio Dept. of Health (ODH) asked about Ohio EPA's rationale for not including cylindrospermopsin as a requirement for routine monitoring since US EPA established a health advisory level for it. "ODH would suggest that even though the detection of cylindrospermopsin in raw water for public water systems has not been common, there is concern that because the blooms change and the mechanisms that trigger toxin production are not well

understood to date, it would seem prudent that some level of cylindrospermopsin monitoring be considered. The frequency of monitoring for cylindrospermopsin could be set based on identified parameters or source water management practices." (Rebecca J. Fugitt, Ohio Dept. of Health)

Response 5: The federal Safe Drinking Water Act requires consideration of three criteria when making a determination to regulate a contaminant in drinking water:

- the potential adverse effects of the contaminant on the health of humans;
- the frequency and level of contaminant occurrence in public drinking water systems; and,
- whether regulation of the contaminant presents a meaningful opportunity for reducing public health risks.

Ohio EPA has applied this approach to each of the four cyanotoxins currently listed in Ohio EPA's HAB Strategy. Microcystins is the only cyanotoxin which currently meets all of these criteria. While U.S. EPA has also issued a Health Advisory for cylindrospermopsin, sampling to date has shown it does not occur frequently in either source or finished water at public water systems. Saxitoxins have been detected in both source and treated waters (below the current Ohio threshold), but there is not currently a U.S. EPA Health Advisory for saxitoxins. Anatoxin-a has not been detected frequently and does not have a U.S. EPA Health Advisory.

Cyanotoxin	U.S. EPA Health Advisory	Commonly occurs in PWS source or finished waters
Microcystins	Yes	Yes
Cylindrospermopsin	Yes	No
Saxitoxins	No	Yes
Anatoxin-a	No	No

To continue to be protective of public health in the absence of regulation for the other cyanotoxins, Ohio EPA will continue to monitor for cyanotoxins other than microcystins in accordance with the PWS HAB Strategy. Results from the cyanobacteria screening conducted by PWSs will be used by Ohio EPA to determine if monitoring for cylindrospermopsin or saxitoxins needs to be conducted by Ohio EPA. Ohio EPA will also continue to work with other states to evaluate the available health effects data for saxitoxins and anatoxin-a.

Monitoring for other cyanotoxins may be required under future rulemaking if the available toxicological and sampling data show regulation presents a meaningful opportunity for reducing public health risks.

Comment 6: "I am aware of only dogs being adversely affected to date in Ohio from suspected algal toxins. I know birds, animals and dogs that have been affected or killed because of other items in our environments (for example, Roundup - Herbicide) but here is little information or publicity presented on those instances or those type products beyond the standard label on practically

everything you buy. These products are allowed and I would imagine there is much misuse and abuse of them." (Sandra O. Vozar, The Village of Fairport Harbor)

Response 6: In collaboration with its local public health departments, ODH has received and investigated human HAB-related illness reports associated with either recreational or drinking water exposures in Ohio since 2010, and has utilized this information to provide public risk-reduction messaging as well as guidance to state partners for strategies which it believes to be protective of the public's health. ODH is aware of probable animal illness and deaths in Ohio related to recreational exposure to cyanotoxins in lakes. However, ODH has not received any reports regarding potential animal illnesses or deaths related to drinking water exposures. Proliferation of some blue-green algae (cyanobacteria) can produce toxins that can cause illness and death in animals. Onset of illness to these toxins is rapid, from minutes to hours with anatoxin or saxitoxin (neurotoxins) and from hours to days with hepatotoxins such as microcystin. In animals such as cattle, sheep, horses, pigs and dogs, clinical signs of acute toxicity include vomiting, weakness, paralysis, rash, seizures or sudden death. The maximum concentration of cyanotoxin in water that is safe for animals has not been determined.

Comment 7: "The Ohio EPA continues to require water utilities to add phosphorus to our water for lead and copper corrosion control and continue to allow homeowners to fertilize their lawns like they have always done. Unfortunately, these big businesses would be upset at their decreased revenue from the products that are adding to this problem. Another big business with sampling is about to be created." (Sandra O. Vozar, The Village of Fairport Harbor)

Response 7: Public water systems may use other corrosion control techniques in place of phosphorus-based inhibitors. However, Ohio EPA has studied the potential impact of phosphorus used as a corrosion inhibitor and found it contributes less than 1% of the total phosphorus load to Lake Erie and is not considered a significant contributor of phosphorus (Ohio Lake Erie Phosphorus Task Force Final Report, Ohio EPA, 2010). Phosphorus was also voluntarily eliminated from lawn fertilizers by Scotts, a leading Ohio manufacturer, in response to concerns.

Comment 8: "During the open house processes and preliminary explanation of the likely proposed regulations, it was explained that only the 30% +/- of PWSs that have previously shown susceptibility to algal issues, such as selective pumping to avoid nutrient loading in reservoirs, or proactive copper sulfate applications. Is it reasonable to lump all surface water utilities together when it can be reasonably believed that much fewer are actually at-risk for harmful algal blooms." (Glenn Marzluf, Del-Co Water Company, Inc.)

Response 8: Microcystins have been detected in the source waters for 75% of the surface water public water supplies sampled so far. That occurrence is high enough to warrant sampling at all surface water public water systems. As noted in the response to Comment 1, sampling frequency can be reduced after collection of

baseline data if the sample results and associated data support a reduction in monitoring.

Comment 9: "Terms used in the proposed regulations are not well defined allowing for broad interpretation. For example, the term 'detection level' is used throughout the rules with an implied assumption that 'detection level' is equal to the current detection level of the ELISA-ADDA test method. Since analytical methods change and detection levels can improve, a specific numeric value (i.e. < 0.3 ppb) should be used to define detection level." (Thomas T. Schwing, Aqua Ohio, Inc.)

Response 9: "Detected" is defined in rule 3745-90-01 as equal to or greater than the reporting limit for the analytical method. The reporting limit for microcystins is established in Appendix B of rule 3745-89-03 as 0.3 µg/L.

Comment 10: "On numerous occasions the rules state …at the 'discretion' of the Director… These statements are too vague and unscientific to justify regulations and utilities cannot determine the true extent or impact of the HAB rules."

"The rule needs to have an agreed upon definition or criteria necessary to support a modified schedule other than at the Director's discretion. This is too ambiguous and not consistent with other action level or MCL reduced monitoring criteria which are clearly spelled out in the rules." (Jeff Swertfeger, Greater Cincinnati Water Works)

"The proposed regulations grant the Director significant discretion regarding certain actions (i.e. reduction in monitoring frequency). However, there are no criteria presented by which the Director will consider and grant variances to those applicable sections of the regulations." (Thomas T. Schwing, Aqua Ohio, Inc.)

"Defining a reduced monitoring schedule would allow systems to decide if it is cost prohibitive to have an analyst certified for testing cyanotoxins. Required monitoring under the Draft Rule could be an economic hardship for smaller surface water utilities forced to conduct year-round sampling for a problem that only occurs a few months of the year." (Philip Van Atta, City of Dayton)

Response 10: The rule provides the director discretion to reduce monitoring frequency after baseline data is collected in an effort to quickly respond to new information and not require ongoing monitoring until the rule can be revised. This provides the quickest opportunity to provide monitoring relief to water systems. It remains Ohio EPA's intent to wait until a year of monitoring is completed to consider revised monitoring schedules; however, the one-year limitation has been removed from the rule to allow flexibility for Ohio EPA to act sooner should it become appropriate. Since very little occurrence data is available for the winter and spring monitoring seasons, it is difficult to predict how monitoring frequency can be modified without additional data. In addition, reducing microcystins monitoring based on qPCR data would only be possible if a strong

correlation is found between gene production and microcystins detection. While Ohio EPA anticipates, based on limited existing qPCR data, that a correlation will be possible, additional data is needed to demonstrate that relationship exists in all Ohio source waters.

The rules also provide the director discretion regarding the requirements for a Tier 1 public notification. In most cases, public notification will be required based on the results of repeats, but the rule allows the director to extend the timeline until additional sample results are received, or require public notification based on the results of resamples, distribution samples or daily samples. This discretion allows the director to act quickly to respond appropriately to the circumstances, including providing relief to water systems in very specific cases.

Comment 11: "With the difficulty that the major water treatment plants are having wouldn't it make sense to give homeowners tax breaks for installing whole house filtration or reverse osmosis systems for their home. Reduce their water bills or something like that when they prove that they have such a system. This would give them an incentive to do this and it would take some of the burden off of the local municipalities until they can come up with long term solutions at the major treatment plants." (Gary Solarik)

Response 11: Public water systems have a responsibility to provide safe drinking water to the public. This burden should not be the responsibility of each homeowner. Further, there is an economy of scale in centralized treatment.

Comment 12: "While the rules package takes a step towards detecting cyanobacterial microcystin toxins in our drinking water, it does not go far enough to ensure a safe drinking supply for Ohio. Given the unprecedented occurrence of HABs across our state, all surface water PWS should be required to develop written protocols for removing microcystin within 30 days after the passage of the rule, rather than waiting 30 days after they detect microcystin in a sample to develop a treatment plan."

"The Public Water Systems' HAB Response is triggered by observation and screening, which is lacking in the proposed rules. Cyanobacterial blooms exhibit exponential growth, and may develop to exceedance levels in less than a week under the right conditions, potentially contaminating a public water supply before detection would trigger appropriate treatment. During peak algae season, cyanobacteria screening and microcystin monitoring of the raw water should be performed to a higher standard in order to detect and prevent this threat. This may include either testing more frequently than once per week, or testing to a lower detection limit, depending on costs, manpower, and technologies available."

There are several "conditions under which undetected blooms may surreptitiously threaten water quality under once-weekly testing protocols:

when water temperature exceeds 65°F (doubling times for cyanobacterial colonies can reach exponential character under these conditions); following periods of high winds when the water column is mixed allowing cyanobacteria at the surface to penetrate to a depth at which raw water inputs are located; following periods of heavy rain or snow melt, when phosphorus loadings increase in the drinking water source supply due to stormwater input; combinations of the first three conditions (may occur more than once from late spring through early fall in the Lake Erie watershed); and whenever blooms are otherwise discovered and reported near drinking water intakes."

"As part of the microcystin treatment protocol submitted by PWSs, the water treatment operator should, taking into consideration up-to-date biological research as well as local source water geology and weather patterns, specify conditions which may be designated as peak event periods. During these peak event periods, more stringent alternative testing protocols should be adopted to allow for the discovery of undetected blooms, though the specific alternative may be designated at the water treatment operator's discretion."

"Spatial and temporal variability in microcystin bloom density makes it inappropriate to follow an assumption of homogenous quality in our water supply. For this reason, if the raw water microcystin concentration exceeds 5 µg/L at any time, monitoring should occur twice daily instead of three days out of seven, including at least one sample taken during typical peak daily sunlight and temperature conditions. Likewise, if microcystin is detected at any level in treated water, monitoring should be increased to twice daily instead of daily. The proposed rule package should also provide guidance on what time of the day to sample based on the lifecycle history of the Cyanobacteria. Finally, the Public Water System should also record their quality control samples and keep on file for ten years."

"By being prepared with monitoring and treatment plans in advance, shifting to more stringent monitoring protocols during certain periods, increased monitoring following detection, and long-range monitoring and analysis, our water suppliers will have a better ability to detect microcystin at our treatment plans before it becomes a human health risk, and give them the resources to better adapt to this emerging threat." (Jen Miller, Ohio Chapter Sierra Club)

Response 12: Requiring submittal of treatment optimization protocols prior to detections in source waters places an undue burden on water systems that are less susceptible to cyanotoxins or are managing cyanotoxins effectively using source control strategies. Ohio EPA will continue to recommend that water systems continue observation and conduct frequent raw water screening (using phycocyanin sensors, conducing phytoplankton identification, and/or monitoring other raw water quality parameters) to better identify and respond to a harmful algal bloom including optimizing treatment. These screening data can also be incorporated into their treatment optimization protocol. However, including observation in a regulatory context is not enforceable, as Ohio EPA would not be able to verify that it is being conducted and actions initiated as appropriate. Also, as noted in the response to Comment 31, cyanobacteria

screening tools other than qPCR cannot be certified by Ohio EPA due to limitations in reproducibility and comparability among equipment and methods.

The raw water monitoring frequency outlined in this rule goes beyond anything that has been required in the past, in part due to the transient nature of harmful algal blooms and health affects posed by cyanotoxins. Given the action level is based on a ten-day health advisory, the frequency is sufficient to protect human health. Further, monitoring is increased to 3 times per week if source conditions degrade (> 5 µg/L microcystins). It is not appropriate to dictate what time of day samples are collected because not all cyanobacteria have the ability to move up and down in the water column and among those that do, different species of cyanobacteria have different diurnal patterns.

Recordkeeping requirements are established in rule 3745-90-07.

Comment 13: The proposed rules "do not account for scenarios in which microcystin levels substantially exceed the action levels of 0.3 µg/L and 1.6 µg/L. Hypothetically, what if a finished water reading comes in at 3.2 µg/L? 6.4 µg/L? The 10-day average model for public safety would seem to break down under these hypothetical scenarios, and the rule as drafted does not provide for an accelerated public advisory requirement or other mechanisms to address this problem."

"Per the draft language and under a worst-case timeline scenario, a Tier 1 public notice would not be issued until approximately 19 days after finished water exceeded action levels." This timeline takes into account the one sample per week from each raw and finished sampling point (in rule 3745-90-03), analysis within 5 days of collection (in rule 3745-90-04), and labs reporting analysis to public water systems no later than the end of the next business day after the analysis is completed (in rule 3745-89-08). "Even under more favorable hypothetical timelines, the draft rule can allow for significant delays in Tier I public notification – beyond 10 days. We urge the agency to tighten the timeframe for compliance and issuance of Tier I public notification." (Nathan Johnson, Ohio Environmental Council)

Response 13: In cases where sample and resample results are elevated above the action level (as in example provided), the director may require issuance of public notice prior to receiving the repeat sample results (see 3745-90-06 (A)(1)(b)). Further, monitoring is increased to 3 times per week if source conditions degrade (> 5 µg/L microcystins).

Comment 14: "I would like to express my severe displeasure concerning the release and comment period for the draft rules for Harmful Algal Blooms (HABs) in the new OAC Chapter 3745-90. I find it unfair and purposely stifling to release draft rules for review and comment while a current HAB season is still underway. The release of the draft rules on September 23 followed by an October 7 webinar for Q&A and an October 23 deadline for comments only allowed for approximately

12 days to review and comment on this matter. Since my primary job is to manage a water plant, review and comment time was in short supply." (Doug Wagner, City of Oregon)

Response 14: The rule-making timeframe was compressed in an effort to release final rules prior to the summer 2016 harmful algal bloom season. Ohio EPA appreciates the time taken by reviewers to comment and has incorporated many recommended changes into the revised rule. We apologize for any inconvenience this accelerated rulemaking may have caused.

Comment 15: "The question was asked in the webinar about submitting previous data. That question was answered with a resounding no from those hosting it. Why did we spend the last 5 years running these tests voluntarily to collect data? Our data proves that toxins are present from late July to early October and nothing outside of that range. Furthermore shouldn't finished water testing be suspended as long as raw water remains in non-detect status? (Doug Wagner, City of Oregon)

Response 15: Paragraph (A)(3) in the current version of rule 3745-90-03 has been revised to include consideration of previous data when modifying monitoring schedules. Ohio EPA is only aware of two water systems in the state with year-round microcystins monitoring data and one of those systems experienced microcystins detections above the action level every month. Ohio EPA is following the approach used with many other contaminants, where more frequent monitoring is required initially, followed by a stepped down reduction once baseline data is established. In response to comments, the rule has been revised to monitor raw water in the winter season with finished water sampling only being triggered if microcystins are detected in the raw water. Given the expected occurrence of microcystins in the summer season, paired raw and finished water monitoring are retained in the rule for that season.

Comment 16: "HAB's have been studied by the science and academic communities for over 50 years and they have clearly established that blue-green algae blooms, cyanobacteria and microcystins flourish in temperatures ranging from 50 to 86 degrees Fahrenheit when combined with high phosphorus and nitrogen concentrations. We have attached two of many recent papers that have been prepared by science and academic institutions tracking microcystin blooms. These papers clearly outline that the threat of microcystin is enhanced throughout the summer months when water temperatures rise and nutrient loadings increase." Papers referenced: 1) Bridgeman, T.B., et al., A novel method for tracking western Lake Erie Microcystis blooms, 2002-2011, J Great Lakes Res (2012); and 2) Timothy T. Wynne and Richard P. Stumpf, Spatial and Temporal Patters in the Seasonal Distribution of Toxic Cyanobacteria in Western Lake Erie from 2002 – 2014, MDPI – Open Access Publishing (12 May 2015). (Ron Wetzel, Ottawa County)

Response 16: Ohio EPA agrees that *Microcystis* blooms typically occur during warmer water temperatures; however, other microcystins-producing cyanobacteria are not as temperature limited and can even predominate under ice. While the western basin of Lake Erie bloom is typically *Microcystis* dominated, other common cyanobacteria have been detected in Lake Erie and other Ohio source waters that have a broader temperature range. In addition, even though *Microcystis* currently is the dominant cyanobacteria genera in the western basin, genera can and do shift given different environmental variables. Microcystins have been detected above the 1.6 µg/L action level for adults year round in Ohio, with some systems experiencing their maximum microcystins concentrations in the late fall and early winter months. Therefore, year-round monitoring is at least initially required to better assess cyanobacteria conditions within each water system's source water. In response to comments, microcystins monitoring frequency from November to April has been reduced to raw water only every other week once there are two consecutive weeks of non-detects in raw and finished, unless raw water detections trigger finished water sampling (see paragraph (A)(2)(b) of the current version of rule 3745-90-03). Raw water cyanobacteria screening has been reduced to every other week, year-round. The director may approve a further reduction in monitoring if baseline sampling data support a reduced monitoring schedule. It remains Ohio EPA's intent to wait until a year of monitoring is completed to consider revised monitoring schedules; however, the one-year limitation has been removed from the rule to allow flexibility for Ohio EPA to act sooner should it become appropriate.

Comment 17: "Akron recognizes that it will take several years for U.S. EPA to complete the regulatory process for developing appropriate standards under the federal Safe Drinking Water Act. Akron fully supports continued testing and data collection for specified cyanotoxins during the interim period." In the interim, "Akron recommends that Ohio EPA and the drinking water utilities that rely upon surface water collaborate to develop protocols, outside of the formal rule making process, for monitoring, testing and reporting specific cyanotoxins. The establishment of protocols, outside of the formal ruling process, will allow Ohio EPA and drinking water utilities to quickly adapt" to U.S. EPA's changing recommendations for health standards, monitoring and testing for cyanotoxins.

"Importantly, the establishment of such protocols, outside of the formal regulatory process is consistent with the requirements of the Ohio Revised Code ("R.C.") Section 3745.50(C), which is the statute that Ohio EPA is relying upon as authority to adopt the Proposed Rules. R.C. Section 3745.50(C) provides the Ohio EPA with the authority to develop 'protocols'. R.C. Section 3745.50(C) does not include any reference to the development of formal rules. In addition, when read in whole, R.C. Section 3745.50 is focused on the Western Basin of Lake Erie." (John O. Moore, City of Akron)

Response 17: These rules will be adopted under the authority of R.C. sections 3745.50(C), 6109.03, 6109.04 and 3745.11(N)(3). R.C. 3745.50 directs Ohio EPA to implement actions to protect against cyanobacteria in public water supplies, among other requirements. While other portions of the statute are limited to

the Western Basin of Lake Erie, the sections that address public water supplies specifically exclude those geographical limitations. These rules are necessary to accomplish the goal, as identified in the law, of protecting our drinking water supply from harmful algal blooms by establishing an enforceable framework for sampling, reporting, and public notification. Public water systems are in the best position to evaluate conditions in real time and to take action quickly, which is essential to ensure people, including sensitive populations, are protected from cyanobacteria in public water supplies. Ohio EPA does not anticipate modifications to U.S. EPA's health advisory for microcystins or development of a microcystins MCL in the near future.

Comment 18: Cyanotoxins are included on the fourth Contaminant Candidate List (CCL4) and will likely be included on the fourth Unregulated Contaminant Candidate List (UCMR4). "Ohio may be well positioned to wait for results of the UCMR4 and a federal determination on regulation of these contaminants instead of proceeding with an independent regulatory rule. Should Ohio proceed with this regulation, will PWSs that have previously collected one year of weekly occurrence data before the implementations of the UCMR4 be exempt from this federal regulation?" (Glenn Marzluf, Del-Co Water Company, Inc.)

Response 18: Given the expectations under R.C. 3745.50, Ohio EPA cannot wait for the results of UCMR 4. In addition, R.C. 3745.50 pertains to all surface water public water systems, not just the subset that will be required to monitor under UCMR 4. Ohio EPA can share the compliance monitoring data collected under this rule with U.S. EPA, but whether they will use the data to exempt systems from UCMR 4 monitoring requirements will be a U.S. EPA decision.

Comment 19: "Raw water toxin concentrations vary from location to location, and vary over time from season to season, year to year. This means that not all utilities are impacted to the same degree with respect to cyanotoxins. There are several 'hot spots' such as Grand Lake/St. Marys and the western basin of Lake Erie; but the majority of Ohio's surface water utilities have not knowingly experienced a severe HAB event; and, because of that, they have no, or very little, raw water cyanotoxin data needed to make treatment decisions. How can a water utility plan for a future even with an unknown raw water contaminant concentration? And, the big question is: should utilities spend a lot of money to optimize for an unknown maximum concentration of toxin that may never occur?"

"To date, OEPA has not provided enough guidance with respect to toxin concentrations needed to determine treated needs and optimization. OEPA has collected a considerable amount of toxin data lumped into a limited mapping system and excel spreadsheet. The mapped toxin values identify a range from <0.3 to >20 µg/L. The spreadsheet data has exceedance in the hundreds of µg/L at those hot spot locations mentioned above. But OEPA has not used that data to project the maximum valve of toxin that may occur at any particular location." OEPA should analyze this database, collect more data and establish the range of toxin concentrations expected at various locations throughout the

state. "This data could then be used by utilities to evaluate what they are likely to experience in the future; and can optimize accordingly."

OEPA needs to do more work before it promulgates this new regulation. "Specifically, they need to: 1. Collect and analyze more toxin data on a locational basis throughout the state; 2. Conduct bench scale toxin adsorption and oxidation tests to determine the chemical doses for various concentrations of toxin; 3. Provide that information in the format of a guidance document that can be used by utilities; and finally, 4. Conduct a cost analysis for various unit process improvements needed to address a potential HAB event." (William D. Gollnitz, City of Lorain)

Response 19: Over the last six years, Ohio EPA and public water systems have analyzed over 3500 raw water samples for microcystins, representing 60% of all surface water systems. 75% of the surface water systems sampled had microcystins detections in their source water. Ohio EPA does not have the capacity to monitor all surface water systems year round, as is expected under Revised Code 3745.50 to be protective of human health.

It is not possible to predict future concentrations of cyanotoxins, which is why ongoing monitoring at some level will be required for most water systems. PWSs that have experienced blooms should plan for a range of conditions and cyanotoxin levels in establishing treatment optimization protocols.

Ohio EPA has partnered with Ohio AWWA to develop a cyanotoxin treatment white paper and has made recommendations to the Ohio Board of Regents to focus applied research on advanced treatment and optimized treatment for cyanotoxins. Each water system, however, is different and should conduct jar and bench scale testing to best optimize their specific plant.

A cost analysis was included in the Business Impact Analysis prepared as part of this rule-making.

Comment 20: "It is very critical for OEPA to recognize and address all potential simultaneous compliance issues that arise from the proposed HAB rules. Some proposed actions are in direct conflict with state and federally mandated primary DW regulations. Utilities need to understand which actions take precedence i.e., federally mandated acute contaminant vs. exceeding a sub-chronic health advisory. Written authorization or an interim waiver should be considered for utilities during HAB events." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 20: Ohio EPA agrees that water systems must maintain compliance with other regulated contaminants in addition to compliance with the proposed cyanotoxin rules. The City of Celina has been able to effectively treat high levels of cyanotoxins while maintaining compliance with all federal requirements for many years. In some instances, it may be necessary in the short term to optimize for sub-acute cyanotoxin removal over a chronic contaminant (e.g. DBPs), but that system should then focus efforts on treatment upgrades

necessary to address multiple treatment objectives so a chronic contaminant exceedance is avoided in the future. Ohio EPA cannot waive federal requirements, although the reason for a violation (optimized treatment for cyanotoxin removal) could be included in the public notification or consumer confidence report.

3745-90-01, Harmful algal blooms - definitions

Comment 21: "What is defined as the algae season?" (Brad Brown, Shelby Water Plant)

Response 21: Cyanobacteria are able to persist year round, but tend to be more prevalent during the warmer months. Therefore, the routine microcystins monitoring has been split between May 1st and October 31st, and November 1st and April 30th. The details of this split are defined in rule 3745-90-03.

Comment 22: Explain what 'other requirement' means in paragraph (A) because it is very subjective and subject to interpretations. (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 22: A revision to the definition of action level was made for clarification.

Comment 23: Revise the definition of cyanobacteria to the following, *"…and may produce cyanotoxins which at sufficiently high concentrations can pose a risk to public health."* (John O. Moore, City of Akron)

Response 23: A revision to the definition of cyanobacteria has been made.

Comment 24: "Why is Microcystin the only toxin to be defined in this section? Are there no concerns for the other toxins that may be released?" (William D. Gollnitz, City of Lorain)

Response 24: Please see response to Comment 5.

Comment 25: "…action levels could be easily construed as exceeding a NPDWR (i.e., MCL). It is recommended to find an alternative term to preserve the true intent of USEPA's action, e.g., 'Advisory Level.' Moreover OEPA should also state that the 'action levels' are based on a 10-day exposure to a specific group in the population." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 25: Ohio EPA specifically used the term "action level" (rather than MCL), in order to indicate that exceedance of the level is not a violation, but rather a trigger for follow up actions. The use of this term within the HAB rules is parallel to and consistent with its meaning under the lead and copper rules. In fact, the following definition of action level must be included in the Consumer

Confidence Reports in accordance with OAC rule 3745-96-02: "Action level": the concentration of a contaminant which, if exceeded, triggers treatment or other requirements which a water system shall follow.

Ohio EPA would rather use a term currently in use, so long as its use is consistent with the commonly understood meaning, rather than introduce a new, separate term with the same general meaning.

The action levels in OAC rule 3745-90-02 were revised to include a reference to U.S. EPA's Health Advisory guidance and a comment was added referencing the 10-day exposure.

3745-90-02, Harmful algal blooms – applicability and action levels

Comment 26: "The proposed rules reference Action Level trigger values at which require specific actions that must be taken. What scientific studies were conducted to support the establishment of the trigger values?"

The proposed action levels are broader and more stringent than what is required to protect public health. "The action levels are based on the presence of *any* microcystin, not just microcystin-LR. The test method does not differentiate between the different microcystin cogenes. In addition, the proposed rules do not consider that the health effects are related to exposure time. Where are the evidence based studies that provide the science for such a stringent requirement? Because the ELISA-ADDA testing method measures all microcystins Action Levels may be triggered more often than actually required to protect the public health. Will these false positive monitoring results create a lack of public confidence in the regulating agency and regulated communities?" (Thomas T. Schwing, Aqua Ohio, Inc.)

The action levels, "expressed as total microcystin levels, may be unnecessarily stringent and may be more than is required to protect public health. For example, the action level of 0.3 µg/L total microcystins is the detection level for currently available analytical methods. Scientific research on the health effects of microcystins is based upon levels of microcystin-LR, and international health-based guidelines for microcystin-LR are significantly higher than 0.3 µg/L. The US EPA health advisory is based upon research on the health effects of microcystin-LR only."

"Ohio EPA should consider revising the 0.3 µg/L microcystin action level for vulnerable populations upwards to be more in line with international standards, and to an action level based upon the presence of microcystin-LR only. To be consistent with the scientific research on the health effects of microcystin, Tier I public notifications should be issued only in the presence of microcystin-LR and at levels more in line with the international consensus."

"If Ohio EPA decides to maintain the action level of 0.3 µg/L total microcystins, the action level should be consistent with the US EPA health advisory, which

applies only to bottle-fed infants and young of pre-school age." Other populations identified as susceptible "should be included in the public notification language as Ohio EPA has proposed, but not referenced in the action level itself." Ohio EPA should consider eliminating in rule 3745-90-02(A)(1), all references to populations except bottle-fed infants and young children of pre-school age. (Richard C. Westerfield, City of Columbus)

Response 26: As noted in the response to Comment 2, the microcystins action levels are based on U.S.EPA's health advisory levels, which were subjected to multiple rounds of scientific peer review. U.S. EPA based the health advisory concentrations on toxicological information available for Microcystin-LR, but recommended the concentrations be applied to all microcystin congeners to be protective of human health. Ohio EPA's application of the action level to all microcystin congeners is consistent with federal guidelines. U.S. EPA's Drinking Water Health Advisory for the Cyanobacterial Microcystin Toxins recommends that certain sensitive populations may want to consider following the recommendations for children pre-school age and older. After reviewing the available data, the Ohio Department of Health recommended including some of the select sensitive populations in the children pre-school age and younger advisory.

Comment 27: "Public water systems serving a limited population may/should be able to justify a less stringent monitoring schedule and action level based upon controls on water usage and population constituency. This is particularly true in light of the fact that the US EPA health advisory levels are based upon oral ingestion, as identified in the Draft Rule Summary, and not total consumption." (Aaron McCoy, Campbell Soup Supply Co.)

Response 27: The action level is based on peer reviewed oral ingestion exposure calculations, and should not be varied based on water system type. Even in cases where children are not served by the water system, the tiered advisory would be necessary to be protective of other sensitive populations such as pregnant women and those with liver or kidney disease.

Comment 28: "The detection limit of the ELISA test is 0.3 µg/L which means that the test cannot detect any concentration lower that value. In the past, for other test results, the detection limit is typically the reportable value. How can the detection limit and the action level be the same?" (William D. Gollnitz, City of Lorain)

Response 28: The ELISA-ADDA method detection limit (MDL) will vary based on the precision of the analyst running the test. Ohio EPA's Division of Environmental Services has achieved MDLs of 0.09 µg/L using the ELISA Microcystins-ADDA method. The reporting limit is always set at a concentration greater than the method detection limit, to ensure the concentration can be reliably achieved at a high degree of confidence. For microcystins, the reporting limit is set at 0.3 µg/L. The ELISA Microcystins-ADDA method requires analysts to demonstrate they

can achieve an MDL that is less than the reporting limit. Further, since the action level is 0.3 µg/L (one significant digit), an exceedance of that level would not be triggered until finished water concentrations were 0.345 µg/L or greater, providing a buffer between finished water detections and action level exceedances.

Comment 29: In paragraph (A), "please include a statement that exceedance of a single action level does not result in a regulatory violation. (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 29: Ohio EPA specifically used the term "action level" (rather than MCL), in order to indicate that exceedance of the level is not a violation, but rather a trigger for follow up actions. The use of this term within the HAB rules is parallel to and consistent with its meaning under the lead and copper rules. Ohio EPA does not consider it necessary to include a statement that exceedance of an action level is not a violation.

<u>3745-90-03, Harmful algal blooms – monitoring requirements</u>

Comment 30: Will an Ohio EPA representative be at the water treatment plant every week to collect cyanobacteria screening samples for the first year? (Orin McMonigle, Operator of Record for Sandusky)

Response 30: No, public water systems will be required to collect and ship samples to Ohio EPA Division of Environmental Services (DES) for analysis during the first year.

Comment 31: The city of Sandusky currently identifies cyanobacteria in their raw water approximately three days per week from May to October. It is believed this information is valuable and will be lost with the new rules, and that it is unreasonable to use qPCR in its place. (Orin McMonigle, Operator of Record for Sandusky)

Response 31: Ohio EPA encourages water systems to continue to use other screening tools (e.g., phycocyanin sensors, algal identification, etc.) to be aware of changes in source water quality and make timely treatment adjustments. These other screening tools, however, cannot be certified by Ohio EPA due to variability in equipment and calibration that limits reproducibility and comparability of the data, and do not include quality control parameters. In the case of phytoplankton identification, certified reference material does not exist so there is no way to ensure reproducibility of results or quality control. qPCR is not intended as a substitute, but as a screening tool to direct Ohio EPA monitoring of other cyanotoxins that may pose a risk to human health. Since qPCR methods include certified reference materials and standards, they allow

confidence in the data and may eventually be useful in reducing frequency of cyanotoxin monitoring.

Comment 32: "Ohio EPA appears to have eliminated commonly accepted science-based tools to evaluate water quality conditions as a trigger for conducting targeted ELISA-ADDA analyses. Specifically, raw water algae identification counts, pH, Phycocyanin and Chlorophyll concentration, chlorine demand, and filter run times are being eliminated as screening tools in favor of an unproven test method (qPCR). Cleveland water will continue using these screening tools for operational control, regardless of whether Ohio EPA recognizes the data for screening purposes. Please explain why Ohio EPA has eliminated these science-based approaches."

The Agency has provided State Revolving Fund monies to public water systems to fund equipment purchases (microscopes, sondes), algae identification classes, etc. These activities also included developing the programs with the public water system staff. "Please explain why the Agency is no longer accepting these screening techniques, particularly for water systems that have experienced chemists and biologists."

"We request Ohio EPA consider using finished water algal toxin detections (or lack thereof) for establishing reduced monitoring. If a surface water treatment plant routinely shows that they are capable of removing/destroying algal toxins, then they should be eligible for reduced monitoring." (Alex Margevicius, City of Cleveland)

"Although Ohio EPA has promoted grant expenditures for algae monitoring equipment, it appears Ohio EPA does recognized the use of this purchased equipment to be useful tools for water treatment plants (WTP) to develop site specific raw water monitoring plans for individual WTP to trigger when increased raw water testing is appropriate." (Thomas T. Schwing, Aqua Ohio, Inc.)

Response 32: Ohio EPA encourages the continued use of other screening tools to evaluate source conditions and optimize treatment; however, as noted in the response to Comment 31, these other screening tools cannot be certified by Ohio EPA. The rules have been revised to include consideration of screening and treatment data for a possible reduction in monitoring frequency.

Comment 33: "Multiple raw water sampling points should be treated as one if the points are close enough in the source water and are representative of the same water prior to treatment." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 33: That is the intent of the rule. "Raw water sampling point" is defined in rule 3745-90-01 as "each plant intake in use prior to any treatment, or another raw water sampling point acceptable to the director". If multiple sampling points

are representative of the same source water, Ohio EPA would accept an alternate sampling point.

Comment 34: In paragraphs (B)(2)(b) to (c) and the table, "the term *non-detection* should be replaced with *0.3 µg/L* which is consistent with the current method. As newer and better methods become available with very low detection limits, detecting at a very low concentration should not trigger the actions described."

"In paragraph (B)(4)(a), "the term *not detected* should be changed to *below 0.3*." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 34: "Detected" and "detection" are defined in rule 3745-90-01 as equal to or greater than the reporting limit for the analytical method. The reporting limit for microcystins is established in Appendix B of rule 3745-89-03 as 0.3 µg/L. As new methods become available, Ohio EPA may need to reevaluate the reporting limit. Until then, this revision is not necessary because non-detection and not detected already means below 0.3 µg/L.

Comment 35: "Testing outside the season seems unreasonable because cyanobacteria of any quantity is visible and noticeable. Operators using raw water sources with problems November to April would record raw water quality issues. Off-season occurrence should be treated as innocent until proven guilty, not the other way around." (Orin McMonigle, Operator of Record for Sandusky)

Response 35: Water systems in Ohio have experienced off-season cyanotoxin producing blooms without noticeable visual bloom or other indicators.

Comment 36: "If you have two reservoirs, are we going to be required to test both and how often if we are using just one reservoir? How long will we have to test the first year?" (Brad Brown, Shelby Water Plant)

Response 36: The rule only requires active intakes in use to be monitored. Public water systems may choose to monitor reservoirs to assist with reservoir management activities, including algaecide application, but additional source water monitoring is not required by rule. The monitoring frequency was reduced in response to comments (see revised rules for details).

Comment 37: "If Cyanobacteria are not detected during the weekly screening process, why waste the time and money sampling for toxins? And, if raw water toxin levels are below detection, why waste the time and money for sampling for toxins in finished water? Has the OEPA estimated a cost for this additional testing for each surface water utility?" (William D. Gollnitz, City of Lorain)

Response 37: The primary use of qPCR data will be to direct additional monitoring by Ohio EPA of other cyanotoxins not included in this rule that pose a threat to human

health. If, after baseline monitoring, the qPCR data is shown to have a strong correlation with microcystins detections, it may be acceptable to reduce microcystins monitoring frequency. More data is needed prior to making that determination. It remains Ohio EPA's intent to wait until a year of monitoring is completed to consider revised monitoring schedules; however, the one-year limitation has been removed from the rule to allow flexibility for Ohio EPA to act sooner should it become appropriate.

Based on comments, the routine monitoring frequency has been revised to raw water only in the November to April season once there are two weeks of non-detects in both raw and finished water, unless raw water detections trigger finished water monitoring. Given the higher occurrence of microcystins from May-October, paired raw and finished water monitoring is required during that season. Cost estimates are included in the Business Impact Analysis.

Comment 38: Raw water analysis with the ELISA ADDA method does not need to be conducted weekly throughout the year, but rather during periods in which it is reasonably expected to find algal toxins based on water temperature. "Finished water ELISA ADDA monitoring should only be required when the raw water analysis indicates raw water toxins are present."

"When a system, such as Cleveland Water, has never had an algal toxin detection in the raw water, requiring weekly raw sampling for qPCR analysis is unnecessary and poses a questionable use of public funds. Public monies should be better targeted to do analyses when toxin-producing cyanobacteria should be reasonably expected." (Alex Margevicius, City of Cleveland)

Response 38: Some cyanobacteria common in Ohio source waters are capable of producing cyanotoxins in cooler temperatures, even under ice. Microcystins and other cyanotoxins have been detected year-round in Ohio, although limited source water data indicate a higher occurrence in the May through October time period. In response to comments, microcystins monitoring frequency has been reduced in the November through April time period and qPCR screening has been reduced to every other week. Screening data is needed to target Ohio EPA's monitoring for cylindrospermopsin and saxitoxins, cyanotoxins that have been detected in Lake Erie and inland sources of drinking water that may pose a threat to human health.

Comment 39: "Under some action level scenarios, the proposed rule requires that sample analysis be done within 24 hours of collecting the sample. See Proposed OAC 3745-90-03(B)(4). Are the independent laboratories certified and ready for tests other than microcystin? As a practical matter this is not possible for utilities without internal laboratory capability that must mail samples to outside laboratories." (Tyler S. Converse, Ohio Water Utility Council of the Ohio Section AWWA; Edward A. Moore, City of Toldeo)

"Finally, Columbus notes that under some action level scenarios, the proposed rules require that sample analysis be done within 24 hours of collecting the sample. See Proposed OAC 3745-90-03(B)(4). As a practical matter this is not possible for utilities without internal laboratory capability that must mail samples to outside laboratories. It is recommended that the wording be revised to, *As soon as practical and in no event more than forty-eight hours…* to allow for laboratory delays." (Richard C. Westerfield, City of Columbus; John O. Moore, City of Akron)

Response 39: The rule was revised to require analysis within 24 hours of sample collection for daily, resample, repeat and distribution samples. Timely analysis is critical after detections of microcystins in finished water. A new provision was also added to allow for a case-by-case monitoring extension in response to logistical problems.

Comment 40: "Eliminate all wording regarding sampling of the raw water. Only the tap water should be regulated. Concentrations of algal toxins in the raw water can be misleading to the public because raw water numbers have no comparative value to the finish water due to the fact that the algal toxins may be removed by the treatment systems." (John O. Moore, City of Akron)

Response 40: Raw water microcystins monitoring is included to provide the information necessary to optimize treatment, adjust monitoring frequency based on source water conditions, and help minimize finished water microcystins detections. Raw water qPCR data is needed to target Ohio EPA monitoring for other cyanotoxins that may pose a threat to human health.

Comment 41: "Proposed OAC 3745-90-03 requires routine (without the exceedance of an action level) weekly collection of screening samples of raw water, and weekly collection of monitoring samples of raw and finished water throughout the year." Weekly sampling during colder months is too frequent, and would be costly when little algae grows during this time of year and will likely be below detectable limits. Though Ohio EPA will initially conduct the cyanobacteria screening, costs of packing and shipping samples will be expensive. (Richard C. Westerfield, City of Columbus; Alice Godsey, City of Perrysburg; Rick Shaffer, City of Norwalk Water Treatment Plant)

"The City of Norwalk's laboratory is approved to conduct microcystin testing and is able to accept samples from neighboring public water systems. Weekly microcystin testing would become costly for the neighboring PWS, with weekly raw and tap analysis costing nearly $600 a month."

"A better use of resources would be to only require monthly sampling from November to April, with any detections in either cyanobacteria or microcystins triggering weekly sampling." (Rick Shaffer, City of Norwalk Water Treatment Plant)

"Given the limiting effects of cold temperatures upon algal growth, Columbus proposes that in the absence of an action level exceedance, utilities collect screening and monitoring samples of raw water only on a monthly basis from November through April and on a twice per month basis from May through October. If the raw water samples are below action levels, there is no need for finished water sampling. Such a schedule of sampling will be adequately protective of public health given that the Ohio EPA's proposed action levels are based upon US EPA's 10-day exposure limits and not on actual exposure limits." (Richard C. Westerfield, City of Columbus)

Please consider the following modification to the weekly sampling during colder months. "During the colder late fall, winter, and early spring months sampling should be reduced to one week per month. …the first week of the month would be appropriate. Weekly sampling could start in November and continue through April. If during any month microcystin concentration is above a trigger amount specified by the OEPA in the raw and/or the finished water sample, sampling would continue weekly until the concentration drops below a set amount or is below the MDL for two consecutive weeks. Once the toxin level drops below the specified concentration the sampling frequency would resume to once per month and continue monthly though the colder months." (Dean A. Reynolds, City of Alliance)

Response 41: The rules were revised in response to comments. Monitoring frequency was reduced to raw water only every other week from November to April once there are two weeks of non-detects in both raw and finished water, unless raw water detections trigger finished water monitoring. qPCR monitoring was reduced to every other week year round.

Comment 42: Berea has been monitoring their source water since 2006 and has never had a microcystis detection in any of the algae counts/ID's . "This testing and its frequency is unnecessary and unreasonable. Other known contaminants the EPA has required monitoring of, for example LT2-cryptosporidium, which is also deemed to be just as hazardous and uncontrolled at the source, only required monthly sampling. The OEPA should consider reduced monitoring (biweekly or monthly during off-season periods, consider weather, and water characteristics (trigger weekly sampling at pH spikes, or water temp of 68°). The OEPA should at least consider sampling for only the raw water source and trigger the plant tap monitoring once a detection (visual at source) or toxin in the raw water sample has been confirmed." (Sandra O. Vozar, City of Berea)

"The proposed HAB regulation is turning out to be somewhat similar if not more stringent in nature to LT2ESWTR for Cryptosporidium … in that the monitoring and extent of treatment is a function of source water concentrations. As allowed in the LT2ESWTR, after a certain period of monitoring of source and finished water (e.g., two rounds, 6-years apart at least 24 monthly samples over 2 year period), systems should get a waiver from monitoring if the results confirm that the system is not vulnerable or has adequate multibarrier

treatment capabilities to address periodic HABs and cyanotoxins." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 42: Cyanotoxins are produced by cyanobacteria other than *Microcystis*, so a historic absence of *Microcystis* is not a reliable indicator of an absence of cyanotoxins. Some common cyanobacteria capable of producing cyanotoxins can occur in cooler water temperatures, even under ice. Cyanotoxins have been detected year-round in Ohio source waters.

The rules were revised in response to comments to reduce microcystins monitoring frequency in the November to April time period and reduce qPCR screening to every other week year-round. In addition, there is a provision in the rule that permits for a further reduction in monitoring frequency based on sampling data, treatment information, and a consideration of additional screening data.

Comment 43: "In the case of Ohio EPA's proposed regulation, weekly samples would be required at all raw and treated surface water treatment plants or consecutive PWS receiving water from out-of-state suppliers not regulated by Ohio EPA. Just by numbers alone, this is 26-times the number of samples required by the proposed state regulation compared with typical requirements of a federal Unregulated Contaminant Monitoring Rule. When cyanotoxins have been discussed as part of UCMR4, never was there talk of weekly testing. Most discussion of cyanobacteria and cyanotoxins acknowledged the *seasonal* nature of their occurrence. Therefore, a possible sample strategy might be to have samples concentrated on warm weather months such as 4 consecutive months, e.g. June – September." (Thomas T. Schwing, Aqua Ohio, Inc.)

Response 43: Cyanotoxins have been detected year-round in Ohio source waters and in some instances water systems experienced their maximum microcystins concentration in the November through April time period. Monitoring frequency has been reduced in the November through April time period in response to comments, but given the existing occurrence data sampling cannot be eliminated in that season at this time. Monitoring schedules may be further reduced if sampling data support that reduction. It remains Ohio EPA's intent to wait until a year a year of monitoring is completed to consider revised monitoring schedules.

Comment 44: "Columbus proposes the following monitoring schedule (this schedule assumes Ohio EPA will maintain the action levels in the current proposed rules):

Total Microcystin (µg/L)	**Sample: Raw Water**	**Sampling: Finished Water**	**Sampling Frequency: November through April**	**Sampling Frequency: May through October**
≤ 5.0 µg/L (Raw Water)	Yes	No	Monthly	Every other week
≥ 0.3 µg/L but	Yes	Yes	Weekly	Weekly

≤ 5.0 µg/L (Raw Water)				
> 5.0 µg/L (Raw Water)	Yes	Yes	Three times per week	Three times per week
≥ 0.3 µg/L (Finished Water)	Yes	Yes	Three times per week	Three times per week

"Columbus proposes that Tier I public notification will not be required unless three (3) consecutive finished water samples under the schedule proposed above are ≥ 0.3 µg/L (or ≥ 1.6 µg/L) total microcystin. Such a schedule will be protective of public health, will avoid unnecessarily burdening the public, will be consistent with the US EPA 10-day exposure limits that are the basis for Ohio EPA's proposed action levels, and will allow water utilities to adjust treatment."

"As currently written, the proposed rules treat the action levels as acute health levels. This in inconsistent with United States and International guidelines and will result in unnecessary burdens being imposed upon the public due to premature or unwarranted public notifications." (Richard C. Westerfield, City of Columbus)

Response 44: In response to comments, microcystins sampling frequency has been decreased from November through April to raw water only every other week once there are two weeks of non-detects in both raw and finished water, unless microcystins are detected in the raw water and trigger finished water sampling. In addition, raw water qPCR screening was decreased to every other week year round.

The response to finished water detections outlined in the rule is consistent with U.S. EPA's "Recommendations for Public Water Systems to Manage Cyanotoxins in Drinking Water", which calls for collection of a repeat sample within 24 hours and daily sampling until finished water concentration are below quantification in at least 2-3 consecutive samples. U.S. EPA also recommends public notification if the repeat sample results exceed the health advisory concentration.

In accordance with rule 3745-90-06(A), in most instances a Tier 1 public notice will not be required unless the action level is exceeded in the routine, resample and repeat samples.

Comment 45: "It appears Ohio EPA is requiring qPCR sample collection by all public surface water systems as a means of data gathering. This should be done as a UCMR, not as compliance monitoring." (Alex Margevicius, City of Cleveland)

"The qPCR test is being used as a research tool for information collection without a defined end or criteria for reduced monitoring, unlike UCMR compounds which have limited impact and a definite end time. OEPA has not

demonstrated sufficient occurrence of these types of toxins to require open-ended monitoring."

"Open ended weekly monitoring for microcystin and qPCR is too frequent and overly burdensome… the frequency of monitoring should be reduced to monthly and with a defined end point of one year. Upon evaluation of these data, appropriate on-going monitoring can then be determined. Establishing the criteria for reduced monitoring and the determination of what the reduced monitoring will be is consistent with other reduced monitoring requirements for MCLs and action level monitoring in the OAC." (Jeff Swertfeger, Greater Cincinnati Water Works)

"Columbus proposes that screening sampling frequency remain at monthly water sampling without regard to the action level exceedances. If the purpose of the weekly screening is to determine occurrence of toxin producing algae, then OEPA should follow procedures used by US EPA for the UCMR. Historically, the most frequent required sampling by US EPA has been monthly, not weekly, to determine occurrence. Columbus also proposes putting sunset language in the proposed rules as to monitoring and screening frequency. Columbus proposes a date certain for terminating these requirements at which time Ohio EPA will have reviewed available data and be in position to require more appropriate data-driven screening and monitoring schedules. (Richard C. Westerfield, City of Columbus)

Response 45: The frequency of cyanobacteria screening via qPCR has been reduced to every other week in response to comments. The primary purpose of the qPCR screening data is to direct additional monitoring by Ohio EPA of cyanotoxins not covered in the rule to be protective of human health. Since the multiplex qPCR assay Ohio EPA is currently evaluating also includes the microcystins production gene, the frequency of microcystins monitoring may be able to be reduced if a strong correlation between the microcystins production gene and microcystins occurrence exists. It remains Ohio EPA's intent to wait until a year of monitoring is completed to consider revised monitoring schedules; however, the one-year limitation has been removed from the rule to allow flexibility for Ohio EPA to act sooner should it become appropriate.

Comment 46: "A possible monitoring strategy, limited to a one year time period, is suggested: All surface water systems shall initially sample for cyanobacteria screening (qPCR analysis) and also perform microcystins analysis on raw and finished waters. If the qPCR is positive and the microcystins analysis is negative then continued weekly screening with weekly microcystins testing until microcystins are detected or qPCR becomes negative. If qPCR and microcystins are both negative then continue weekly screening with the microcystins testing reduced to monthly. During this reduced monitoring other surveillance indicators such as visual bloom observation, microscopic analysis, pH swings, pigments, etc. (as noted in current OEPA Harmful Algal Bloom Response Strategy) would continue with observations indicative of cyanobacteria populations or positive screening results triggering the increase of microcystins analysis back to weekly."

"The concept of screening is to be able to evaluate a large population in an effective and efficient manner so the more detailed and involved diagnostics is reserved for only those that screening flags as needing further follow-up. The proposed rule does not take advantage of this screening filter concept and requires microcystins analysis on all samples."

"Based on current and scientific and health knowledge base, analytical capabilities and the social environment, year round weekly algal toxin screening may be necessary in Ohio but the rules need to be flexible enough to adjust this resource intense effort as we learn more. We suggest a harmful algal monitoring strategy should begin with surveillance, followed by screening, which is followed by toxin analysis when warranted. (Richard C. Lorenz, City of Westerville)

Response 46: See response to Comment 45. If a strong correlation can be made between microcystins production genes and microcystins detections, a reduced monitoring schedule similar to what was proposed can be considered (see paragraph (A)(3) in the current version of rule 3745-90-03). This paragraph was also revised to allow for the consideration of other indicators when modifying monitoring schedules. It remains Ohio EPA's intent to wait until one year of monitoring before considering revised monitoring schedules.

Ohio EPA will continue to encourage public water systems to perform regular visual surveillance and screening of their water sources with other tools such as phycocyanin sensors. However, including visual surveillance in a regulatory context is not enforceable, as Ohio EPA would not be able to verify that surveillance is being conducted and actions initiated as appropriate.

Comment 47: Clarification is needed on paragraph (B)(2) of this rule based on the potential holding time for analysis after routine sampling [five days according to rule 3745-90-04(A)(2)]. Is the increased sampling three days per week after a raw water microcystin detection of 5 µgL applied the same week at the detection or in the following week?

Also, the term for cyanobacteria screening data should be clarified, if the Agency's intent is to use cyanobacteria monitoring data to evaluate microcystin monitoring schedules. (Aaron McCoy, Campbell Soup Supply Co.)

Response 47: Clarification was added to the rule in response to comments. Paragraph (A)(2)(c) was revised to require increased monitoring to begin the following week.

Comment 48: The "action level" as cited in paragraph (C) of this rule is not well defined in regard to the action levels identified in rule 3745-90-02(A). (Aaron McCoy, Campbell Soup Supply Co.)

Response 48: Paragraph (A)(4) of the current version of the rule has been revised to reference both of the action levels in rule 3745-90-02.

Comment 49: Sampling required of consecutive public water systems needs to be clarified and consistent. "It appears the intention is for consecutive systems to collect samples for microcystin in response to an action level trigger within the wholesale system, but the requirements as written in the proposed language are not clear." Examples are as follows:

Paragraph (A) of rule 3745-90-02 refers only to microcystins unless additional monitoring is required as stated in paragraph (B). Additional monitoring is not defined.

As proposed, paragraph (C)(4) of rule 3745-90-03 would require the surface water system and all consecutive water systems to collect and analyze samples within 24 hours. It also states that additional monitoring may be required based on sampling results. The rule does not specify what analyses or additional monitoring is expected.

Draft language in the policy, Limited Distribution of Public Notice proposes an option for conducting "ongoing daily distribution system sampling for cyanotoxins and chlorine residual…" testing as a means of limiting the distribution of the public notice.

"BCWS recommends that any required sampling for consecutive systems be limited to only the entry point(s) from the wholesaling surface water system that had the action level trigger as that would be the most helpful in regards to determining the extent of the spread of HAB within the connected systems and with determining the limits for issuing the public notice. Additional sampling with the consecutive system should remain as an option for the consecutive system, not a requirement." (Julie Frazier, Butler County Water and Sewer Dept. or BCWS)

Response 49: Requirements for consecutive systems have been clarified in the rules. Distribution sampling must be conducted in accordance with the consecutive system's contingency plan. Ohio EPA has intentionally provided flexibility in distribution sampling requirements so each PWS can design a sampling plan that best fits their system. If the consecutive system does not intend to limit the extent of an advisory within their distribution system and instead chooses to issue a system-wide advisory, limited distribution sampling may be acceptable. This will be a system by system decision.

Comment 50: It was requested Ohio EPA provide clarification on the notification of multiple consecutive systems. Paragraph (C)(4) of this rule requires the system with the action level exceedance to notify all consecutive systems served by the water system. Does this notification include consecutive systems supplied by the system directly connected to the water system with an exceedance? "Will the

systems directly connected to the system with an exceedance be expected to notify their own consecutive systems regarding triggered sampling within the three hour time frame after receiving notification from their supplier? Additionally, will this notification requirement extend to private water systems or be limited only to public water systems?"

"For example: Surface water system A supplies water to consecutive system B which then supplies water to their consecutive systems C & D plus one or more private water systems. If the supplying system A exceeds the action level, will they be required to notify systems B, C, D and possibly the private water systems or will system A only notify system B who will then be required to notify systems C, D and possibly the private systems?" (Julie Frazier, BCWS)

Response 50: Notification of consecutive water systems is the responsibility of the wholesale system supplying the water and should be contained within the wholesale system's contingency plan. In the example provided, Ohio EPA would expect system A to notify system B, and system B to notify systems C and D. Ohio EPA's jurisdiction does not include private water systems, but we would encourage communication about any health risks between the public and private systems. If public notification is required, each PWS has to notify all customers served. In the example provided, system B would have to notify all its customers, including the private system.

Comment 51: "The language in draft rule is vague, *'…the routine microcystins monitoring frequency may be decreased at the discretion of the director if the cyanobacteria screening data…'*. Is it just the routine microcystin monitoring that may be decreased or is it possible that the cyanobacteria screening monitoring may be decreased as well? Although OEPA's intent appears to be sound, there is no real guarantee of relief for systems that prove there is little value in weekly sampling." (Glenn Marzluf, Del-Co Water Company, Inc.)

The Ohio Water Utility Council has a comment on paragraph (B)(3) of this rule, which may allow for decreased monitoring. "The Ohio Section believes this language is too open-ended. If the director chooses not to intervene and reduce the monitoring frequency, it will continue on a weekly basis indefinitely per the proposed rule language."

Similarly in paragraph (A), "the language implies weekly cyanobacteria screening will go on indefinitely regardless if such long-term weekly sampling proves to be valid or valuable. This open-ended monitoring requirement should be modified. Ohio EPA should put sunset provisions into the rule that will end the screening and monitoring requirements by a date certain, at which time Ohio EPA may amend the rule to require appropriate screening and monitoring schedules that are protective of public health based upon the data Ohio EPA collects during the initial implementation of the rules." (Tyler S. Converse, Ohio Water Utility Council of the Ohio Section of AWWA; Edward A. Moore, City of Toldeo)

Response 51: The rule was clarified in response to comments. Frequency of both microcystins and screening monitoring may be modified based on a consideration of microcystins and screening data, treatment information, and other surveillance monitoring data collected by the public water system. If the screening data collected as part of this rule is not valid or useful for targeting additional cyanotoxin monitoring the director can modify the monitoring schedule and no longer require screening data collection. A sunset provision is therefore not necessary, and would be detrimental if screening data proves valid and valuable during the first year of monitoring.

Comment 52: The City of Dayton is designated as a Ground Water Under the Influence of Surface Water (GWUI) system. "Because of sand filtration and low oxygen conditions in groundwater, the City of Dayton and other GWUI systems are not likely to have contamination events related to algal blooms. If an algal bloom were to occur in a City of Dayton groundwater recharge system, the toxin would be significantly reduced or eliminated by filtration through sand and gravel, and by low oxygen level conditions. Also due to the volume of water supplied by Dayton's source water aquifer, the toxin would be diluted below detection limits prior to the water being pumped from the aquifer. Thus, the HAB Draft Rule monitoring requirements should be reduced for Dayton and other GWUI systems to account for the lack of susceptibility to cyanotoxins for GWUI systems." (Philip Van Atta, City of Dayton)

Response 52: GWUI systems are considered by rule to be surface water, and subject to the same requirements. Cyanotoxins are not removed by sand filtration and are not affected by low dissolved oxygen concentrations. The monitoring schedule can be modified after baseline data is collected based on microcystins and screening data, treatment information, and other surveillance data collected by the water system. It remains Ohio EPA's intent to wait until a year of monitoring is completed to consider revised monitoring schedules; however, the one-year limitation has been removed from the rule to allow flexibility for Ohio EPA to act sooner should it become appropriate.

Comment 53: "Please provide some guidance on the number of distribution samples required, including the flexibility for systems to analyze a limited number of samples (e.g. w/shortest travel time) first. This will allow the best use of resources in the shortest amount of time. If a problem is confirmed, then the remaining samples could be analyzed to determine the extent of the problem." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 53: Distribution sampling should be conducted in accordance with the public water system's contingency plan. The public water system has the flexibility to select the sampling locations that will be most helpful to the system in assessing the effects on distribution and possibility to isolate portions of distribution and limit the extent of a public notice.

3745-90-04, Harmful algal blooms – analytical methods and reporting

Comment 54: "…the freezing and thawing required in the testing procedure will prove difficult in the initial and repeat sampling, and all samples will need to be analyzed or shipped early in the day. For smaller systems this may add an undue burden to a time strapped water plant operator." (Philip Van Atta, City of Dayton)

"Whether in-house or through a lab, microcystins analysis fails part of the time. Freezing-thawing and the test is time intensive. It can take several days to more than a week to get results. What kind of leeway is there for failed and delayed tests? Also, what is the penalty if the original sample was improperly collected (such as forgetting to quench or forgetting to collect the field duplicate which have both occurred in our lab and delayed results) but still run?" (Orin McMonigle, Operator of Record for Sandusky)

Response 54: The rule allows 5 days from collection to complete analysis for most samples (24 hours for daily samples, resamples, repeats and distribution samples). As with other required sampling, Ohio EPA recommends sampling early in the monitoring period to allow time for any analytical or collection errors. In most circumstances, sample collection or analytical errors will result in unacceptable data, and another sample must be collected and analyzed to fulfill the monitoring requirement. There are some limited circumstances under which sample data may still be accepted following a sample collection or analytical error. The ELISA-ADDA Method has been revised to clarify when samples may be reported as qualified, and when sample results are not acceptable and new samples must be collected and analyzed. The revised method also no longer requires the collection of field duplicates. If a sample is not collected and analyzed within the required time frame, the water system will receive a monitoring violation which requires public notification.

Comment 55: "Cleveland Water does not see the value of continuing the freeze-thaw sequence of the ELISA ADDA test methodology. The primary mechanism for cyanobacteria removal has always been coagulation/sedimentation to keep the cell structure intact. Creating a 'worst case,' unlikely scenario of all intracellular toxin being released is overly conservative. Until scientists have a better understanding of the chemistry involved with what make cyanobacteria produce and release toxins, we should continue monitoring realistic scenarios that involve public health. This monitoring should include extracellular toxin only." (Alex Margevicius, City of Cleveland)

Response 55: Measuring both intracellular and extracellular toxins is important because it is critical to ensure treatment is removing all forms of the toxin present in source water, in particular because if any intact cells pass through treatment and are consumed, they would be lysed within the human body and the toxin would be released. While this is unlikely given typical water treatment processes, it is still possible and an important assurance. This is consistent with U.S. EPA recommendations. Ohio EPA recommends water systems conduct both total

and extracellular analysis of raw water and throughout the treatment train to better optimize treatment for both intact cells and extracellular toxin.

Comment 56: "What are the other methods for the identification of cyanobacteria acceptable to OEPA? Are data sondes with chlorophyll/phycocyanin probes (using fluorescence) acceptable; or does one need to confirm the occurrence of cyanobacteria using DNA (qPCR)? If weekly qPCR is going to be the only method, why are we installing data sondes near our intake?"

"What are the reporting limits for all of the various instruments being used to detect cyanobacteria?"

"What is the cost of qPCR analysis? Is OEPA going to charge utilities for the weekly tests during the first year? What is the estimated cost that laboratories will charge after they have been certified?" (William D. Gollinitz, City of Lorain)

Response 56: At this time, the only method used for cyanobacteria screening will be qPCR. Water quality sondes and other screening methods such as phytoplankton identification and enumeration provide very valuable information to water systems, enabling them to respond to changing source water conditions and make timely treatment adjustments. Phycocyanin measurements can be useful for monitoring trends within an individual lake, but since phycocyanin measurements can vary substantially based on environmental conditions, such as turbidity, setting a uniform standard to measure against is not possible. These other screening tools cannot be certified by Ohio EPA due to variability in equipment and calibration that limits reproducibility and comparability of the data. In the case of phytoplankton identification, certified reference material does not exist so there is no way to ensure reproducibility of results or quality control.

Ohio EPA will be performing cyanobacteria screening by qPCR at no analytical cost to the public water systems for at least the first year following the rules effective date. The public water systems will be responsible for costs of collection and shipment of samples for cyanobacteria screening. The estimated cost of qPCR analysis, once laboratory capacity is established, is estimated to be $70-$183 per sample.

Comment 57: "What are the names of certified labs to do the testing and what would the cost be?" Also, "we have a Sonde probe which is installed portable in our raw water line so we can take it out into the reservoir. How accurate are the results and can we use them for any of the required testing?" Last of all, "most outside labs can't even do this testing yet and need to purchase equipment and the get certified and this takes time and a huge capital investment." (Brad Brown, Shelby Water Plant; Joe Bottegal, City of Steubenville)

Response 57: A list of acceptable laboratories for analysis of microcystins by ELISA will be posted on the Certified Laboratories website for at least one year from the rules

effective date. After one year from the rules effective date, a list of certified laboratories will be posted on the Certified Laboratories website for analysis of microcystins by ELISA and cyanobacteria screening. Outside (commercial) laboratories are not required to become certified, but may view the capital investment to become certified as a business opportunity.

Results obtained by a water quality sonde will not be acceptable for reporting as this will not be a certified method. However, as noted in the response to Comment 31, sonde data are useful for optimizing treatment and reservoir management, and may be considered by Ohio EPA when evaluating a possible revised monitoring frequency.

Comment 58: Ottawa County used Ohio EPA grant money to purchase a Water Quality Sonde Unit, which provides the water system with "real time monitoring of raw quality data. Ottawa County is able to monitor specific conductivity, pH, chlorophyll, blue-green algae, dissolved oxygen and temperature. …chlorophyll and in particular, blue-green algae, are used as primary Sonde Unit indicators to provide a real time early warning system that cyanobacteria may be impacting our source water. If the Sonde Unit data were ever to increase out its normal range, we would then test for microcystin in an effort to determine what was going on." (Ron Wetzel, Ottawa County)

Response 58: As indicated in the response to Comment 56, water quality sondes are very useful to water systems for operational purposes, but the method is not able to be certified. Therefore, Ohio EPA cannot establish a monitoring framework using sondes as a trigger for microcystins monitoring. Monitoring for microcystins will be required by the rule independent of the results of any sonde data. However, Ohio EPA has expanded the provision for a revised monitoring frequency to allow consideration of any sonde data.

Comment 59: **"**The City of Norwalk and others have invested in training lab analysts to become proficient in identifying algal and cyanobacteria species. It would be more efficient for properly equipped labs to first screen samples for cyanobacteria, then forward samples to Ohio EPA if cyanobacteria is present for DNA testing using the qPCR method. Norwalk would be willing to screen samples for surrounding systems that would likely be bringing samples for microcystin testing at the same time." (Rick Shaffer, City of Norwalk Water Treatment Plant)

Response 59: At this time, the only method used for cyanobacteria screening will be qPCR. Cyanobacteria identification and enumeration provides very valuable information to water systems, enabling them to respond to changing source water conditions and make timely treatment adjustments. It is, however, not a method that can be certified by Ohio EPA due to subjectivity in the analyst and lack of certified reference material that limits reproducibility and comparability of the data.

Comment 60: This rule requires water utilities to analyze samples for monitoring with ELISA analytical methodology. It is the only test method accepted by Ohio EPA. The test has a known bias and does not differentiate between the various microcystin congeners. Any detection would be assumed to be microcystin-LR causing a response. "The ELISA method cited by Ohio EPA is a poor method and does not meet the requirement of the Safe Drinking Water Act Section 1401(1)(d) which requires acceptable methods and QC testing procedures to be used in setting MCLs and treatment techniques. The ELISA method is an unreliable method with a + / - 40% accuracy that tests for the presence of total microcystins, not microcystin-LR only, the toxin upon which all United States and International health based exposure guidelines are based. The ELISA method may result in false positive results or in positive results for microcystins that may not have harmful health effects. Ohio EPA should not rely upon the ELISA method, but develop a certified analytical method for determining the presence of microcystin-LR by way of a much more accurate mass spectrometry process (such as: HPLC and LC/MS/MS). By providing for a more accurate test method for microcystin-LR, the significant social costs of public notification under the proposed rules will be minimized and will be imposed only in the presence of an actual threat to public health." (Jeff Swertfeger, Greater Cincinnati Water Works; Thomas T. Schwing, Aqua Ohio, Inc.; Richard C. Westerfield, City of Columbus; Philip Van Atta, City of Dayton; Alex Margevicius, City of Cleveland)

"We have been doing in house testing for 5 years voluntarily, not only for ourselves, but for other systems in the area. We can with certainty that the testing is not only expensive, but the testing method itself is questionable at best. ABRAXIS is the only approved provider for testing supplies whereby creating a monopoly. More important is the fact that these tests have a failure rate in our lab of almost 50% even with an accuracy of plus or minus 40%! As a monopoly, ABRAXIS' profit will triple by including the off season testing and every surface water system in the State of Ohio will gain absolutely nothing." (Doug Wagner, City of Oregon)

The ELISA-ADDA method is only available through a single manufacturer and codifying it in rule creates a monopoly. (Philip Van Atta, City of Dayton)

"ELISA-ADDA is the only analytical method allowed in the proposed regulation. Many researchers seem to consider the ELISA technique as a <u>screening</u> technique. That is, use ELISA, but alternative techniques should be used to confirm results."

"Product brochures from Abraxis also suggest that the ELISA testing results be confirmed. *As with any analytical technique (GC, HPLC, etc.), positive results requiring regulatory action should be confirmed by an alternative method.* – This is a quote from an Abraxis brochure: Microcystins-ADDA ELISA (Microtiter Plate), product number 520011."

"Ohio EPA's documents also appear to cast doubt on the utility of the ELISA method as a regulatory tool. In the *Procedural Tips* section of Ohio EPA guidance (August 2014), "extreme caution" is offered when running the analytical method." Several cautions were listed in attempt to avoid human errors. "In an updated document from Ohio EPA, similar cautions and details of the ELISA method are outlined. It is stated that the accuracy of the ELISA is "highly dependent" upon analyst technique. This is not a phrase that should be associated with an analytical method that is proposed for important testing to comply with a regulation." Because of the issues of cross reactivity and interferences, many researchers recommend confirming ELISA results with another analytical method. In section 11 of the Ohio EPA's analytical methodology for ADDA by ELISA, additional cautions about ELISA were outlined.

"Reliance on a single analytical method that may not have undergone rigorous validation studies is being proposed to be used in situations that will likely have significant implications. These implications involve triggers for action: additional expensive sampling; public notification to customers; increased costs for water treatment; potential economic disruption; and false positive representation of public health protection." (Thomas T. Schwing, Aqua Ohio, Inc.)

Response 60: See response to Comment 2. Further, multiple vendors distribute the microcystins ELISA-ADDA kit. U.S. EPA Method 544 (for six individual congeners) requires use of a proprietary internal standard that is only available from one source and is in limited supply.

Despite what the Abraxis brochure indicates, neither Ohio EPA nor U.S. EPA requires confirmation of results with an alternative method for any other regulated contaminant. All analytical methodologies are highly dependent on analyst technique, and must be performed by trained and qualified individuals who take caution to avoid human error, which is why Ohio EPA is requiring microcystins analyses to be conducted by a laboratory certified by or acceptable to the director.

Comment 61: "Greater Cincinnati Water Works has had problems meeting the QA/QC requirements for the ELISA method. While we continue to work with OEPA staff to determine the problem, to date over 30% of our samples have failed the QC. This is significant as we are a sophisticated laboratory with skilled analysts and certified by OEPA DES for this analysis, yet we have a high level of QC failure. This is a great concern since the rule requires weekly analysis there is a high probability that laboratories, even commercial labs, may not be able to complete analyses that pass all QA/QC within the holding time. If this is the method that is dictated, it is essential that the OEPA accept qualified data for reporting during the routine, weekly monitoring. This is occasionally done for NPDES and other type of reporting on the surface water side. We understand there are qualifiers included in the analytical methodology but we are not clear at what point use of these qualifiers becomes a violation. Please clarify the acceptable use of qualified data for meeting these rules." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 61: Ohio EPA has revised the "Ohio EPA Total (Extracellular and Intracellular) Microcystins – ADDA by ELISA Analytical Methodology version 2.2 (Ohio EPA DES 701.0)" to clarify which deviations result in acceptable data that may be reported with qualifiers, and which deviations result in unacceptable data (need to recollect/reanalyze or receive a monitoring violation). Qualified data is accepted for routine monitoring and MDL studies. The qualifiers have been limited to J and CL. The method requires the use of a J qualifier on all results if the concentration of either the QCS or LCRC is outside of the acceptable range.

Comment 62: Paragraph A "states that the OEPA DES will perform analyses except when the director determines there is insufficient lab capacity. We assume this is a punctuation error and the intent will perform analyses if there is insufficient lab capacity. Please re-word this paragraph." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 62: This section has been clarified.

Comment 63: "It appears that the state of Ohio (at its cost) will conduct one year of weekly qPCR testing at all surface water plants. Given the reliability and reproducibility associated with the qPCR analytical test method, how reliable and valuable will the data be that is collected? Will public water systems be required to perform the qPCR testing after the first year? Is this a study to verify the efficacy of the ELISA-ADDA test results being collected concurrently or collection of data to justify the proposed regulations?"

"Analytical methods used in compliance typically undergo validation studies. When regulatory agencies such as USEPA approve analytical methods for compliance testing under SDWA, rigorous Quality Control and inter-laboratory studies are performed. What studies have been conducted demonstrating the validation of the ELISA-ADDA analytical method?" (Thomas T. Schwing, Aqua Ohio, Inc.)

Response 63: The data provided by qPCR will primarily be used to determine if additional toxin analysis, beyond microcystins, is needed. After certified laboratory capacity is established but at least one year from the rule effective date, public water systems will be required to collect and send samples to a laboratory certified to perform cyanobacteria screening by qPCR, so long as the method is proven reliable for screening purposes. qPCR will not verify the efficacy of the ELISA-ADDA test results. qPCR will be performed in tandem with analysis of microcystins as a screening tool in order to determine if additional toxin analysis needs to be conducted by Ohio EPA, such as cylindrospermopsin and saxitoxins. In addition, reducing microcystins monitoring may be possible in the future based on qPCR data if a strong correlation is found between gene production and microcystins detection.

The ELISA MC-ADDA kit is U.S. EPA ETV certified. Validation is part of the ETV certification process. In addition, USGS selected the ELISA MC-ADDA kit for use in the National Lakes Assessment sample analysis after a comprehensive review of available ELISA kits and comparison of ELISA MC-ADDA and LC-MS/MS results. USEPA has also included ELISA MC-ADDA as a monitoring tool for UCMR4.

Comment 64: "The Minimum Reporting Level (MRL) of 0.3 ppb in the ELISA-ADDA method makes the process a presence/absence test. This is much too close for comfort when it comes to regulatory decisions taking treatment process action, and issuing Public Notices."

"Ideally, a more sensitive analytical method would provide a wider margin of error/safety between the Health Advisory and the Minimum Reporting Level. Because the Health Advisory is at the same concentration as the MRL, the ELISA method has effectively become a presence/absence test. That is, any detected concentration ("hit") of microcystin in the finished water is considered a problem regardless of the particular microcystin cogenes present." (Thomas T. Schwing, Aqua Ohio, Inc.)

Response 64: See response to Comments 2 and 28. The reporting level is driven by the analytical method, and the action level is driven by the available toxicological data. While it would be preferable to have a greater difference between the two levels, there is not currently a more sensitive method that also measures total microcystins. As noted in the response to Comment 2, Ohio EPA considers the ELISA-ADDA method to be reliable, even in the range close to the reporting level. Alternative methods continue to be evaluated and validated and may be acceptable for use in the future.

Comment 65: "What science-based criteria did Ohio EPA use select qPCR over other analytical methods? We have significant concerns based upon conversations we have had with Northeast Ohio Regional Sewer District. They have been conducting in-house testing with qPCR and their results do not appear to provide adequate information for water systems to make informed treatment decisions. It is our understanding this is due to an inadequate knowledge base of qPCR results." (Alex Margevicius, City of Cleveland)

"qPCR methods are absolutely not to a point to be acceptable for regulatory compliance and regulatory monitoring. These methods have been examined for potential use in other regulatory monitoring such as Cryptosporidium monitoring for LT2ESWTR and found not to be acceptable by the USEPA. The requirement to monitor by this method seems to be an attempt by the agency to place the burden of a research project on the backs of water utilities with no defined end to the monitoring." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 65: The qPCR assay proposed in these rules will be used as a screening tool, with follow-up cyanotoxin monitoring based on gene detection of viable and non-

viable cells. qPCR data generated by NOAA using Lake Erie samples has shown genes are detected one to two weeks prior to detection of cyanotoxins, demonstrating the sensitivity of qPCR and utility as a screening tool. *Cryptosporidium* monitoring is concerned with viable cells only, as *cryptosporidium* is an infectious agent that poses a concern to human health. In contrast, cyanotoxins can persist after the lysis of cyanobacterial cells, so cell viability is not necessary to cause negative effects on human health. qPCR will allow for detection of both viable and non-viable cells while microscopy will only allow for detection of viable cells.

Cryptosporidium monitoring under the Long Term 2 Enhanced Surface Water Treatment Rule (LT2 ESWTR) was originally based on immunofluorescence assay microscopy with verification by 4',6-diamidino-2-phenylindole (DAPI) staining and differential interference contrast (DIC) microscopy using U.S. EPA methods 1622, 1623 and 1623.1. The first *cryptosporidium* qPCR kits were available in 1998; however, they were not quantitative and not equivalent to microscopy. Therefore they were not approved for LT2 ESWTR monitoring. Molecular typing by qPCR was later reevaluated to determine if it would fit into U.S. EPA method 1623. However, there was poor resolution at low oocyst concentrations; qPCR was unable to distinguish between 1, 2 or 5 oocysts. Switching to qPCR would not allow for comparison of results between round 1 and round 2 monitoring because the comparison would be like apples to oranges, due in part to qPCR's detection of genetic material in non-viable cells. The two procedures, microscopic identification and qPCR, do not currently produce comparable data for the purposes of LT2.

Comment 66: There is concern with the qPCR method used for screening cylindrospermopsin, saxitoxins, and anatoxin-a. "Although the samples may contain the genetic materials for these species, the material may not produce a viable organism. The qPCR method requires amplification and isolation of the gene of interest. These toxins are genetically closely related, and primer specification is a concern. Since these samples will not be collected in a sterile environment, non-specific genetic contamination potential is greatly increased. Depending on the sensitivity of the primer design and quencher this may falsely amplify the amount of genetic markers present in the sample. The primers will need to be written to only identify gene sequences expressed exclusively by each toxin, and without sequencing overlap or nesting to effectively quantify the presence of the organism. The Draft Rule does not clearly define at what levels additional monitoring will be required for these toxins or allow for outside verification of results." (Philip Van Atta, City of Dayton)

Response 66: The commercial quantitative multiplex cyanobacteria qPCR assay that Ohio EPA is currently evaluating has primers designed to target the specific genes responsible for the production of microcystins (mcyE gene), cylindrospermopsin (cyrA gene), and saxitoxins (sxtA gene). Multiple genera and species/strains of cyanobacteria have been tested and show that the targeted gene sequence is conserved regardless of cyanobacterial source. The assay includes an internal amplification control (cyanobacteria specific 16S rDNA) and certified DNA reference standards. Tailored TaqMan probes are specific to the targeted genes

sequences. The assay will detect genetic material present in non-viable or dead cells, which is important since toxins can also persist after cell lysis. More information on the multiplex qPCR assay is available in the article "A multiplex qPCR targeting hepato- and neurotoxigenic cyanobacteria of global significance" published in Harmful Algae 15 (2012) page 19-25. The results of the qPCR analysis will be used to determine if Ohio EPA needs to conduct additional monitoring for cyanotoxins other than microcystins.

Comment 67: "qPCR methods detect DNA or cDNA produced by cells and not the toxins themselves. There are many processing steps that a cell undertakes to translate the cDNA into actual toxin and the presence of cDNA does not necessarily equate to toxin production. Cell conditions, growth phase, and external stimuli could also greatly influence cDNA and toxin levels. Could the OEPA please provide references documenting a relationship that may have been established relating qPCR methods to actual toxin detection? Does the Ohio EPA have any data from systems in Ohio that may have shown this relationship or the lack of such relationship? Could the agency please provide a reference to an accepted method for performing qPCR analyses? Interested parties cannot fully comment on the use of this analysis without any information on the reference method." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 67: qPCR will be used as a cyanobacteria screening tool and will not be used to determine toxin levels. qPCR will be used to isolate the need for additional toxin analysis, beyond microcystins. The qPCR analytical method is being refined and will be provided prior to certifying labs in this method. Additionally, Ohio EPA tested a small number of Ohio environmental samples using a commercially available quantitative multiplex qPCR assay. The assay detected toxin-production genes in every sample that contained microcystins or saxitoxins and did not detect toxin-production genes in samples from blooms that were not producing toxins. NOAA tested the same multiplex assay on Lake Erie samples and found they detected toxin-production genes one to two weeks prior to detecting cyanotoxins in the water samples, demonstrating the qPCR assay is sensitive enough to be used as an effective screening tool. More information on the multiplex qPCR assay is available in the article "A multiplex qPCR targeting hepato- and neurotoxigenic cyanobacteria of global significance" published in Harmful Algae 15 (2012) page 19-25.

<u>3745-90-05, Harmful algal blooms – treatment techniques and requirements</u>

Comment 68: Treatment technique requirements assigned equally for raw and tap detections seems unscientific. "Some affected public water systems have been asking regulatory agencies to provide documentation and research as to the efficacy and efficiency of various treatment methods to deal with cyanobacteria for several years. The major efficiency of various treatment of cyanobacteria will most likely tweak their existing treatment processes. The regulatory agencies need to provide resources to accomplish research on cyanobacteria treatment methods instead of requiring PWSs funded by ratepayers to provide this basic

research." (Orin McMonigle, Operator of Record for Sandusky; Alice Godsey, City of Perrysburg)

Response 68: The purpose of the requirement to submit treatment protocols is to ensure water systems are proactively evaluating their treatment and prepared to treat or take avoidance strategies to avoid finished water detections of cyanotoxins. The requirement will most likely be triggered by a detection in raw water. The trigger for a finished water detection was included in the case of a very rare event that the requirement was not already triggered by a raw water detection.

Ohio EPA, U.S. EPA and other local, state and national experts are cooperating to advance the research in cyanotoxin treatment. Many studies are currently underway, including research on potassium permanganate effects on cell lysis and microcystins oxidation, PAC adsorption capacity and dosing recommendations, chlorine degradation rates, effectiveness of advanced treatment technologies, fate and transport of microcystins in the distribution system, and triggers for toxin production.

Research can provide general guidelines on treatment effectiveness, but Ohio EPA recommends that each water treatment plant conduct their own jar testing to optimize processes within their plant. If a plant has GAC, they should consider conducting a Rapid Small Scale Column Test (RSSCT) using their specific water quality and media type at design empty bed contact times to help determine the effectiveness of that barrier on microcystins removal.

Comment 69: "The rule stipulates that a public water system must submit written protocols for treatment changes within thirty days if any amount of microcystin is detected in raw or finished water and to submit plans for source water protection within 120 days if the amount exceeds the 10-day health advisory level of 1.6 µg/L. Treatment changes should not be guided by amounts detected below reporting level where data uncertainty is highest." (Philip Van Atta, City of Dayton)

Response 69: "Detected" is defined in rule 3745-90-01 as equal to or greater than the reporting limit for the analytical method. The reporting limit for microcystins is established in Appendix B of rule 3745-89-03 as 0.3 µg/L. Therefore, the treatment technique requirements do not apply below the reporting limit.

Comment 70: Provide a justification for the selection of 1.6 µg/L of microcystin in the raw water sample as the trigger for submission of a cyanotoxins general plan. (Aaron McCoy, Campbell Soup Supply Co.)

Response 70: 1.6 µg/L is the adult health advisory level established by U.S. EPA. Public water systems need to be able to demonstrate an ability to deal with source water concentrations above the adult health advisory level. They may be able to demonstrate their existing practices are sufficient, or may determine that additional measures are needed. This provision has been revised from one

sample greater than 1.6 µg/L to more than one greater than 1.6 µg/L within a consecutive twelve-month period.

Comment 71: "We discussed our strategy and optimization protocols with OEPA personnel who documented our HAB plan in September of this year. Are we expected to submit the same information within 30 days of the rule in addition to the report that has already been filed in 2015?" (Orin McMonigle, Operator of Record for Sandusky)

Response 71: Yes, treatment optimization protocols will be required to be submitted under this rule. Any previous efforts to document and optimize treatment will be helpful in fulfilling this requirement.

Comment 72: A question was received about whether optimization protocols are in addition to the general plan or whether the general plan includes protocols as the next step. Also, it was asked whether the general requirements refer to 2015 raw water detections. (Orin McMonigle, Operator of Record for Sandusky)

Response 72: These are separate documents with different triggers. Treatment optimization protocols describe how the PWS will respond to changing source water conditions using existing treatment. The cyanotoxin general plan is a more holistic look at avoidance strategies, source water protection and treatment (including future improvements). The treatment optimization protocols may be triggered on data collected after July 16, 2015. The cyanotoxin general plan will not be triggered until data collected after the effective date of rule meets the criteria in the rule.

Comment 73: "If a system has conducted demonstration of performance or uses a treatment technique that is sufficient to address Cyanotoxins, there should a waiver or a significant reduction in the monitoring frequency as stated in 3745-90-03." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 73: As with other regulated contaminants, monitoring is necessary to ensure that treatment is effective. There are some provisions for reductions based on treatment capabilities in the rules, but Ohio EPA does not expect to waive all monitoring requirements.

Comment 74: "*Finished water detection* should be replaced with *Finished water detection greater than 0.3 µg/L*" in paragraph (B). (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 74: This change is unnecessary. "Detection" is defined in rule 3745-90-01 as equal to or greater than the reporting limit for the analytical method. The reporting limit for microcystins is established in Appendix B of rule 3745-89-03 as 0.3 µg/L.

Comment 75: "The rule calls for a trigger level of 1.6 µg/L at the source water (for surface water plants) to comply with the requirements of 3745-91-02(C). What is the rationale behind such a conservative number? All surface water plants (where HAB rules are applicable) are required to comply with the IESWTR/LT2 through removal and inactivation. Based on the AWWA resources, a SW plant with simple disinfection step alone with a free chlorine concentration of 2.0 mg/L with at least 60-min of contact time at a pH of 7.5 should bring microcystin concentrations at or below the method detection level. These calculations were based on a mixture of microcystin congeners. This example is illustrative as a typical example not taking into account physical removal of microcystin. So the proposed trigger level appears to be too stringent and arbitrary and thus needs to be revised and must be based on sound science." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 75: The assumption of a pH of 7.5 represents a limited number of surface water systems which operate at that pH, with a number of systems operating at a finished water pH over 8. The contact time (CT) required for destruction of microcystins increases as pH increases, with a significant increase necessary for a pH over 8. Other variables such as temperature and competing oxidant demand can affect the amount of CT required.

The scenario provided describing disinfection CT (2.0 mg/L with 60 minutes of contact time) yields a CT of 120 mg/L- min. For disinfection, a 0.5 log inactivation of Giardia represents the most challenging goal, microbially. Microbial disinfection becomes more difficult as pH increases, temperature decreases, free chlorine residual decreases, and clearwell levels are low and flowrate is high through the basin. The same is assumed to hold true for microcystins reduction. However, achieving a 0.5 log reduction of Giardia with CT does not necessarily translate to being able to reduce total microcystins to a level below detection.

A 2.0 mg/L free chlorine residual at a pH of 9, requires at least a CT of 83 mg/L-min for 0.5 inactivation of Giardia. The value of 120 mg/L-min, used in the example, is more than the 83 mg/L-min required for 0.5 log reduction of Giardia; however, for microcystins, this CT, using the AWWA calculator at pH of 9, temperature of 10 degrees C, CT of 120 mg/L-min will only provide destruction down to 0.6 µg/L. From this table top analysis, it appears an additional treatment barrier is necessary beyond chlorine contact to bring levels of microcystins down to below detection.

Any CT calculator for destruction of microcystins is limited by the availability of research on the type of microcystin variant used and available input parameters for rates of reaction. Only a handful of the microcystin congeners have been studied in regard to reaction rates and the effect of chlorine on their destruction. The rule requires compliance with a health advisory level for total microcystins. The other congeners' reaction rates with chlorine are not well defined and as a result, a more conservative approach with a trigger level of 1.6 µg/L is used.

Further, microcystins have been detected in the finished water from an Ohio community water system at a concentration of 0.58 µg/L when the raw water concentration was 1.0 µg/L. Finished water pH was 8.5. The samples were collected on the same day and time, but were not true paired samples. This real-world example helps demonstrate that lower microcystins concentrations in the raw water may still be capable of breaking through conventional treatment.

Each public water system needs to be able to demonstrate an ability to deal with source water concentrations above the adult health advisory level. They may be able to demonstrate their existing practices are sufficient, or may determine that additional measures are needed. Note: this provision has been revised from one sample greater than 1.6 µg/L to more than one sample greater then 1.6 µg/L within a consecutive twelve-month period.

Comment 76: Clarify which action level applies in paragraph (B)(1) since there are two specified in the rules package.

"It is not clear what would be required for the demonstration that the existing practices are sufficient to prevent finished water action level exceedances: reports based on literature, bench studies, actual plant performance under microcystin incidents? More specific process guidelines would be necessary for the evaluation of the treatment processes." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 76: The rule has been revised to indicate both action levels apply. Ohio EPA is developing guidelines to provide assistance to water systems in developing both the treatment optimization protocols and cyanotoxin general plan.

Comment 77: The Ohio Water Utility Council is "very concerned about submitting detailed treatment protocols and general plans to the OEPA from a security perspective unless they will commit to protect these protocols and plans from public information requests. These documents will contain very sensitive information on the ability of water systems to adjust treatment for chemical and biological contaminants which could very easily be used for intentional acts of terrorism. We believe that OEPA has the ability to protect sensitive infrastructure information including emergency response plans. If the OEPA cannot or will not protect these documents, we recommend that water systems develop them and keep with their emergency procedures and allow OEPA to review (but not keep a copy of) these documents." (Tyler S. Converse, Ohio Water Utility Council of the Ohio Section AWWA; Jeff Swertfeger, Greater Cincinnati Water Works; Edward A. Moore, City of Toledo)

Response 77: The rule has been revised to indicate that treatment optimization protocols and cyanotoxin general plans are not public records pursuant to section 149.433 of the Revised Code.

Comment 78: The Ohio Water Utility Council is "concerned that the use of the term 'protocol' implies that the utility must have an extremely detailed treatment 'recipe' response. Depending on circumstances, treatment response may need to be varied. The term protocol should be changed to strategy, guideline or similar wording. The utility can then provide generalized response strategies. This will also ensure that the utility is not cited for a treatment technique violation if they modify their treatment strategy compared to the document." (Tyler S. Converse, Ohio Water Utility Council of the Ohio Section of AWWA; Jeff Swertfeger, Greater Cincinnati Water Works; Edward A. Moore, City of Toledo)

Response 78: It is Ohio EPA's intention that water systems develop and submit detailed treatment 'recipes', or standard operating procedures. Each water system needs to consider, in advance, how it will monitor source water conditions and how, specifically, it will adjust treatment to respond to changing conditions. However, Ohio EPA understands that the utility may need to vary from the written protocols, and will not issue a violation if they modify their treatment strategy compared to the document during a HAB event. The treatment technique violation specified in the rule is for failure to <u>submit</u> the treatment optimization protocols, not failure to implement them as specifically written.

Comment 79: "There already is a requirement for HABs to be addressed in a utility's contingency plan. How much more information will be required for the cyanotoxin general plan and the optimization protocols? OEPA needs to provide more guidance on treatment plant optimization. Should there be some target design level based upon location? For example, our evaluation of the OEPA data indicates that the central basin maximum toxin levels have not exceeded 5.0 µg/L. And, the western basin has maximum values in the 100s µg/L. Should utilities in the central basin be required to provide treatment for concentrations experienced in the western basin?"

"How will a water treatment plant demonstrate optimization without a significant HAB event? The only way to do this would be to purchase stock solutions of toxin and conduct an extensive series of jar tests using raw water spike with toxin, calculate the required chemical feed rates, and demonstrate that the feeders will provide that rate. It would be very beneficial, and more cost effective, if the OEPA would do the jar testing and provide the removal/oxidation data to the utilities. Water utilities, such as Lorain, with limited finances, staff and lab resources, will find it difficult to conduct extensive testing for plant optimization." (William D. Gollnitz, City of Lorain)

Response 79: The requirement for HABs to be addressed in a utility's contingency plan is intended to ensure a utility has carefully planned how it will <u>respond</u> to a finished water detection or action level exceedance, which may include treatment adjustments, but also includes communication strategies (with both the public and emergency response partners), identification of sensitive populations, distribution sampling, etc.

The treatment optimization protocols, on the other hand, are intended to ensure that a utility has carefully considered how to adjust treatment in response to changing source water conditions, to prevent any finished water detections/action level exceedances, so that the contingency plan does not have to be activated.

Ohio EPA is in the process of developing guidelines to provide assistance to water systems in developing both the treatment optimization protocols and cyanotoxin general plan. Utilities will be expected to be able to provide treatment for their typical source water conditions. While Ohio EPA anticipates that demonstration may be made through a combination of research literature and historical data/plant performance, each water system is unique in both source and treatment and it may be necessary in some circumstances to conduct bench studies.

Comment 80: Paragraph (A)(1) "should apply only to finished water microcystin detections." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 80: This requirement is intended to be preventive, and thus the trigger based on raw water detection is appropriate. As noted in the response to Comment 79, each water system needs to consider, in advance, how it will monitor source water conditions and how, specifically, it will adjust treatment to respond to changing conditions.

Comment 81: Paragraphs (A) and (B) "are very confusing in that they seem to require the same actions. Why not simplify this by just saying that a cyanotoxin general plan is required within 90 days after promulgation of the regulation. The general action plan should include a discussion on how the plant is optimized to remove toxins." (William D. Gollnitz, City of Lorain)

Response 81: These are separate requirements with different purposes. The purpose of the treatment optimization protocols is to ensure a water system has considered, in advance, how it will monitor source water conditions and how, specifically, it will adjust existing treatment to respond to changing conditions. The purpose of the cyanotoxin general plan is to ensure that a water system is doing the long-term analysis and planning necessary to address HABs, which could include source water management and avoidance strategies but may also include capital improvements if their current approach is not sufficient.

Comment 82: In paragraph (B)(1), "the general plan needs to be approved in accordance with Chapter 3745-91. It is unclear whether signature by a PE is intended to apply to the general plan. It would be most appropriate to require the general plan be signed and submitted by the Operator of Record. Please include language to clarify that the general plan would be signed and submitted by the Operator of Record." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 82: The general plan does need to be prepared by a professional engineer (PE). The general plan needs to be submitted in accordance with Chapter 3745-91. OAC rule 3745-91-03 (B)(11) specifies general plans not within the scope of the "Guidelines for Design of Small Public Water Systems" (which this is not) must be prepared by a PE. Ohio EPA considers it appropriate for a PE to be involved in preparation of the general plan since an evaluation of existing source(s) and treatment will be necessary and it may include capital improvements. Ohio EPA expects the Operator of Record to also be involved in development of the general plan.

Comment 83: Paragraph (A)(1) of this rule requires systems to develop and submit written treatment protocols, within 30 days of the effective date of the rule, for systems that have detected microcystins in a sample collected between July 16, 2015 and the effective date of the rule. "Please explain why previous sample results are not accepted for the year required but it okay for OEPA to use previous data to force water systems into early compliance by being proactive?"

In respect to the cyanotoxin general plan as outlined in paragraph (B)(1), "there is insufficient research for plants to develop such a plan. No one knows what it takes to remove all the toxins through the treatment process. The only reasonable response is maximizing chemical treatment which is a waste of money. Proper research should be performed before such rules are put in place. Additionally, charging water systems $150 to review these plans I once again a waste of time and money and adding an additional expense to already taxed water systems. Using 1.6 µg/L in raw water as a trigger for notifying OEPA and implementing the plans is both unreasonable and ludicrous. 1.6 µg/L is a finished water indicator is ridiculous. Every water system would handle 1.6 µg/L without altering treatment, a reasonable number would be at least 5 µg/L but preferably 10 µg/L."

Lastly, "the enhanced surface water treatment rule has an exemption from testing for providing treatment that has 5.0 Log removal for Cryptosporidium. The HAB draft rules do not however address plants that provide more than adequate treatment for algal toxins. Shouldn't the same consideration be given to utilities that provide barriers to algal breakthrough? Exemptions should be allowed for approved treatment." (Doug Wagner, City of Oregon)

Response 83: Ohio EPA has expanded the criteria for considering revised monitoring frequencies to include previous microcystins data. Also, the trigger for the cyanotoxin general plan has been revised from one sample greater than 1.6 µg/L to more than one sample greater than 1.6 µg/L within a consecutive twelve-month period.

Ohio EPA, U.S. EPA and other local, state and national experts are cooperating to advance the research in cyanotoxin treatment. Many studies are currently underway, including research on potassium permanganate effects on cell lysis and microcystins oxidation, PAC adsorption capacity and dosing

recommendations, chlorine degradation rates, effectiveness of advanced treatment technologies, fate and transport of microcystins in the distribution system, and triggers for toxin production.

Research can provide general guidelines on treatment effectiveness, but Ohio EPA recommends that each water treatment plant conduct their own jar testing to optimize processes within their plant. If a plant has GAC, they should consider conducting a Rapid Small Scale Column Test using their specific water quality and media type at design empty bed contact times to help determine the effectiveness of that barrier on microcystins removal.

It is necessary to use the best available information to make treatment adjustments, and Ohio EPA is working to make that information available to water systems. Ohio EPA and AWWA Ohio Section are collaborating to update the White Paper on Cyanotoxin Treatment, and Ohio EPA is in the process of developing guidelines to provide assistance to water systems in developing both the treatment optimization protocols and cyanotoxin general plan.

As noted in the response to Comment 75 above, it has been demonstrated that every water system cannot handle 1.6 µg/L in source water without altering treatment. It may be possible for your system to demonstrate your current treatment is sufficient, but it would be inappropriate for Ohio EPA to establish an "exemption" for sufficient treatment without carefully evaluating the treatment in place. As with other regulated contaminants, monitoring is necessary to ensure that treatment is effective. There are some provisions for reductions based on treatment capabilities in the rules, but Ohio EPA does not expect to waive all monitoring requirements.

Comment 84: "We recommend that Ohio EPA not insist on specific treatment in the rules. Instead, we suggest including specific treatment in a policy (HAB strategy). For example, the proposed rule explicitly states to avoid lysing cells. Under certain circumstances (e.g., sub-optimized physical barriers), multiple sequential lysing/absorption steps followed by residual destruction might turn out to be the best strategy. So they type and nature of cyanotoxin treatment should be left to the discretion of the Operator of Record and be not included in the regulations." (Alex Margevicius, City of Cleveland; Jeff Swertfeger, Greater Cincinnati Water Works)

"The rules must allow for site-specific determination of the most effective treatment techniques to prevent algal toxins from contaminating finished water." Paragraph (A) of this rule assumes all water plants are the same and "the present wording can be interpreted as saying all water plants shall avoid lysing cyanobacteria cells. That may not always be the best option. Lysing cells and treating the toxins may be the best option for some plants."

Paragraph (A) should be revised as follows, which would give water plant operators the ability to decide the best option for prevention algal toxins from contaminating drinking water, using existing treatment: *…In developing the protocols, the public water system shall review and optimize existing treatment for microcystins~~, utilizing techniques to avoid lysing~~. The following shall be*

considered as options in developing the best protocol for a particular water plant: avoidance of cyanobacterial ~~cells~~ cell lysing within the water plant, ~~optimize~~ optimized removal of intact cells, ~~optimize barriers for extracellular cyanotoxin~~ optimized removal or destruction of extracellular cyanotoxin, optimize sludge removal, and discontinue or minimize backwash recycling. …

"In Norwalk, the solids contacts clarifiers recycle sludge hundreds of times before the sludge is eventually wasted. A significant sludge blanket must be maintained for this process to work. Each re-cycle of the sludge is another chance for cyanobacteria cells to be lysed." Norwalk Water Treatment Plant believes in their case, because of the constraints in operating the solids contacts clarifiers, that it would be best to purposely lyse any cyanobacteria cells in the reservoir and then treat for the toxins in the plant.

"The plant is capable of feeding up to 120 mg/L of carbon with an exclusive contact time of at least one hour, at design capacity. If any algal toxin got by the carbon, the plant can feed as much as 50 mg/L of sodium hypochlorite, if necessary, to inactivate the toxins in the clearwells before they reach the distribution system." Additionally, the Lower Reservoir (feeding the Norwalk plant) is routinely treated for algae from May 1st to October 1st, limiting the chances of a significant harmful algal bloom. However, Norwalk believes the treatment plant has the capabilities to prevent algal toxins from contaminating the finished water if a harmful algal bloom were to occur in the Lower Reservoir. (Rick Shaffer, City of Norwalk Water Treatment Plant)

Response 84: The list of treatment strategies has been revised to be informative rather than directive, so that water systems can choose the best strategy for their situation.

Comment 85: "Due to the intra and extracellular nature of the toxins, treatment operation response to an event should be flexible and holistic to the water treatment plant (not related to a single unit treatment process when addressing the nature of the toxin). Pre-oxidation, chemical type and dosages, sedimentation, sludge removal, filtration, etc. are all unit process operations that must be evaluated and adjusted to address an event. Hence, 'treatment technique' is not a singular unit process. Response plans to a toxin event should be guidance allowing flexibility to response to the in-situ situation at the time of the event based on the operator in responsible charge's professional judgment. The establishment of a Treatment Technique violation for failure to implement a predefined written document does not allow for the use of professional judgment to implement the best response to a unique event." (Thomas T. Schwing, Aqua Ohio, Inc.)

"Historically, treatment techniques and the violation of them, are normally associated with unit process(s) with numerical performance indicators, e.g., filtration, disinfection,… The best strategy for algal toxin treatment has been proven to be multibarrier – physical removal, adsorption, and oxidation. Considering the intra and extracellular nature of the toxins, it is not realistic to assign a treatment technique violation to multiple unit processes." Within in the rule, treatment technique violations are applied to development, submittal, and adherence to at treatment protocol and general plan. "We believe this is an

inappropriate use of treatment technique." (Alex Margevicius, City of Cleveland; Jeff Swertfeger, Greater Cincinnati Water Works)

Response 85: "Treatment technique" is not intended to mean a singular unit process, but rather is used in a more general context which includes evaluating and adjusting treatment. "Treatment technique" is also used in other rules in a more general sense, such as the Revised Total Coliform Rule where a treatment technique is the "find and fix" approach that occurs through assessments and corrective action.

Each water system needs to consider, in advance, how it will monitor source water conditions and how, specifically, it will adjust treatment to respond to changing conditions. Ohio EPA agrees the response should be flexible and adjustable, and Ohio EPA will not issue a violation if a water system varies from the written protocols at the time of an event. The treatment technique violation specified in the rule is for failure to submit the treatment optimization protocols, not failure to implement them as specifically written.

Comment 86: Omit the entire rule 3745-90-05 on HAB treatment techniques. "It is unnecessary because water treatment plants will seek the most up-to-date advice as to their options to reduce algal toxins. Written protocols are not required for other regulated contaminants. This draft rule overly burdensome and the submittal of additional written protocols can strain the resources needed for other operational concerns." The rule allows systems 30 days from a detection of microcystin to submit their treatment protocols, which is of no immediate value. "Moreover every surface water utility is already required to have a section in its Emergency Operation Plan addressing action to be taken in the event of an algal toxin occurrence. Thus, this rule is also redundant of existing requirements." (John O. Moore, City of Akron)

Response 86: Some water systems have already and will continue to choose to seek advice and implement solutions to address cyanotoxins without this rule. However, this rule is necessary to ensure that all water systems are prepared to prevent finished water action level exceedances, either through their existing practices, optimizing existing treatment or implementing additional measures including reservoir management, avoidance strategies or infrastructure improvements.

As noted in the response to Comment 79, the requirements are separate and different from the requirement to address HABs in your contingency plan.

Comment 87: "The Agency (not just the DDAGW) should be aware and accept that a minimization or elimination of backwash recycling will require variances or exemptions to existing NPDES permits or may cause a discharge from a non-permitted location." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 87: Ohio EPA is aware that treatment adjustments such as elimination of backwash may have an impact on NPDES permits and other discharges. The Division of

Drinking and Ground Waters is working with the Division of Surface Water to determine if a new general permit for emergency backwash discharges is needed and if modifications should be made to existing individual permits to cover emergency discharges of backwash water in response to a harmful algal bloom.

3745-90-06, Harmful algal blooms – Tier 1 public notification and consumer confidence report requirements

Comment 88: Paragraph (B) of this rule should not require consecutive systems to publish the wholesale system's data in their consumer confidence report (CCR) "if they were excluded under a limited area public notice issued by the wholesaling system or if the consecutive system conducted microcystin sampling and did not detect it within their own distribution system." (Julie Frazier, BCWS)

Response 88: The rule has been revised to clarify information must be included in the CCR if an action level was exceeded within the community system.

Comment 89: The Ohio Dept. of Health asked about the process for issuing a do not drink advisory. "Perhaps there is a different administrative or rule process that we are not aware of, but it is not clear that when either microcystin level is exceeded, that a do not drink advisory notice is required to be issued by the public water system for either the sensitive populations at 0.3 µg/L or all populations at 1.6 µg/L. The rule refers to OAC Rule 3745-81-32 Public notification, but this rule does not appear to specify a do not drink advisory specific to microcystins when an action level is detected. Is there a different process that establishes the issuance of the do not drink advisory?" (Rebecca J. Fugitt, Ohio Dept. of Health)

Response 89: Ohio EPA does not specify in rule what actions consumers should take for each specific type of violation that can occur. Rather, paragraph (E) of rule 3745-81-32 establishes content requirements of public notices, including the population at risk (including any sensitive populations), what actions consumers should take, and whether alternative water supplies should be used. 3745-81-32(E)(3) also specifies that the notice shall not contain language which nullifies the purpose of the notice. A specific reference to these content requirements has been added for clarification.

To aid in compliance with the public notification rule, Ohio EPA provides public notice templates for most violations. A PWS may revise the public notice for their specific circumstance, but the changes should be approved prior to issuance by Ohio EPA (or the revised notice may not be acceptable and must be reissued).

Comment 90: The following are recommended revisions. (John O. Moore, City of Akron)

- Change the words harmful algal blooms to algal toxin exceedances. "This rule is not referencing algae in the reservoir but is centered on algal toxin detections in the tap water."
- "Consistent with other drinking water reporting requirements, the health advisory level needs to be exceeded for 10 consecutive days before it is required to be reported in the CCR.
- Revise language in paragraph (B)(3), "…also known as blue-green algae, which under certain conditions (i.e. high nutrient concentration and high light intensity) ~~form harmful algal blooms~~ may produce microcystins.
- Add in paragraph (C), "Consuming water containing concentrations of microcystins at the detected level over a sufficient number of days may result in…

Response 90: Response to each bullet follows:

- Chapter 3745-90 establishes requirements regarding harmful algal blooms not just algal toxin exceedances.
- As noted in the response to Comment 3, extending the time period to 10 consecutive days above the action level before informing the public is not an appropriate interpretation of the 10-day health advisory level.
- Language in paragraph (B)(3) has been revised from "…form harmful algal blooms" to "…may produce microcystins".
- Recommendation was taken into consideration and paragraph (C) has been revised from "at the detected level" to "over the action level".

Comment 91: In paragraphs (A)(1), (A)(4) and (B), "please clarify which action level. 3745-90-02 establishes two action levels."

Also, in paragraph (B)(2) "there is no need to include *highest single measurement*. That is included in the *range of levels detected* in definitions." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 91: A notation has been included, identifying the action levels of concern from OAC rule 3745-90-02(A)(1) and (A)(2). *Single highest measurement* was included for consistency with requirements in OAC rule 3745-96-02 and the federal Consumer Confidence Report rule.

Comment 92: "Would a Tier I notification be avoided if the reanalysis and resample were below detection, and the repeat sample collection and analysis was not completed within 24 hours? According to 3745-90-03 that would be a Tier 3 notification." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 92: The rule has been revised to clarify that failure to take resamples or repeats requires a Tier 1 public notice, unless a written extension or waiver is granted. Note: the requirement for reanalysis has been removed from the rules.

Comment 93: "Please consider updating the Standard Health Affect Language to more accurately present information known or unknown to date and how this 10 day health advisory level was chosen. Although algal toxins may cause a gamut of symptoms, I am unaware of any specific case where a person or group of people have definitely contracted such symptoms from algal toxins at levels that you have determined."

Does the action level assume one is drinking the recommended 8 glasses per day for 10 days (drinking toxin contaminated water)? "What if you drank 1 tsp per day for 10 days? Would you become severely ill? People become alarmed because they brush their teeth or inadvertently are exposed prior to being aware of a notice and become sensitized that they are ill or exposed to permanent health affects due to minor contact with the water. Please elaborate that similar to all unsafe practices – eating raw eggs, undercooked meats, and pharmaceuticals, there could be health effects." The drafted health affects language "misrepresents the risks and exposures and make drinking public water system produced water anywhere in this country inferior and represents it as risky or less safe than bottled water and much of that misconception is due to EPA required language." (Sandra O. Vozar, City of Berea)

Response 93: The standard health effects language should not be expected to stand alone; it is just one part of the entire message contained in the public notice. Paragraph (E) of rule 3745-81-32 establishes content requirements of public notices, including the population at risk (including any sensitive populations), what actions consumers should take, and whether alternative water supplies should be used. Ohio EPA has developed public notice templates which aim to communicate the risks associated with microcystins. These templates are contained in the PWS HAB Strategy and will be updated for the 2016 season.

Comment 94: Clermont County Water Resources Department offered the following revision to paragraph (A)(1)(a), specifying Tier I public notification requirements: "*…until additional repeat results are received <u>or unless it can be demonstrated that the action level established in rule 3745-90-02 of the Administrative Code was not exceeded for a period of 10 or more consecutive days</u>.*" (Lyle G. Bloom, Clermont County)

Response 94: As noted in the response to Comment 3, U.S. EPA's 10-day health advisory level is the level *at and below* which adverse effects are not expected over a 10-day exposure. This cannot be interpreted to mean that individuals can tolerate any amount above that level for 10 days. Ohio EPA has allowed for some limited time to adjust treatment before an advisory is required, where conditions are appropriate. However, extending the time period to 10 consecutive days above the action level before notifying the public is not an appropriate interpretation of the 10-day health advisory level.

Comment 95: "The U.S. EPA health advisory does not reference persons with 'pre-existing liver conditions'. Any public notification for exceedances of 0.3 µg/L action level should distinguish between the populations to which the US EPA health advisory

applies, bottle-fed infants and young children under school age, and populations that US EPA identifies as being 'susceptible' to the health effects of microcystins." Columbus proposes the following revisions to paragraph (C) of this rule: *…"Consuming water containing concentrations of microcystins at the detected level may result in abnormal liver function, diarrhea, vomiting, nausea, numbness or dizziness in this population. ~~Children younger than~~ Bottle-fed infants and young children of pre- school age~~,~~ should not consume water containing concentrations of microcystins at the detected level. ~~Pregnant~~ Pregnant women, nursing mothers, the elderly, immune-compromised individuals, ~~those with pre-existing liver conditions~~ and those receiving dialysis treatment may be more susceptible than the general population to the health effects of detected levels of microcystins."* (Richard C. Westerfield, City of Columbus)

Response 95: The U.S. EPA health advisories indicate that pregnant women, nursing mothers, those receiving dialysis treatment, the elderly and immune-compromised individuals may be more susceptible than the general population, and recommends these individuals may want to consider following the recommendations for children.

Ohio has specifically included pregnant women, nursing mothers, and those receiving dialysis treatment in the action level at 0.3 µg/L. Ohio has also added those with pre-existing liver conditions to the action level at 0.3 µg/L. Ohio concurs with the recommendation that elderly and immune-compromised individuals may want to consider following the recommendations for sensitive populations under the 0.3 µg/L action level. The Centers for Disease Control and Prevention has stated their support of Ohio's position to provide additional protections to pregnant women, nursing mothers and those receiving dialysis treatment or with pre-existing liver conditions when the action level of 0.3 ug/L is detected.

3745-90-07, Harmful algal blooms – recordkeeping

Comment 96: The following are recommended revisions. (John O. Moore, City of Akron)

- Revise the title to replace harmful algal blooms – recordkeeping with "Microcystins – recordkeeping" to more accurately describe the records.
- In the first introductory paragraph, delete "cyanobacteria screening and…".

Response 96: Recordkeeping will be required for both microcystins and cyanobacteria screening.

3745-89-05, Requirements for maintaining laboratory certification

Comment 97: "Would microcystin certification be required before the Rules get finalized and the weekly microcystin sampling is also required? Please clarify whether the current approval is sufficient for 3 years with annual submission of MDL studies. According to 3745-89-03 (A)(3)(e)(iv) the limited chemistry fee covering this analysis would be effective on 5/1/17?" (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 97: Rule 3745-90-04 has been revised to allow for the current acceptance process to continue until one year from the effective date of Chapter 3745-90. Rules 3745-90-04, 3745-89-03 and 3745-89-04 allow for certification of total microcystins and cyanobacteria screening to begin one year from the effective date of Chapters 3745-89 and 3745-90. As with all other laboratory certifications, certification for total microcystins and cyanobacteria screening will expire within three years from the effective date.

The Ohio EPA DES method 701.0, "Ohio EPA Total (Extracellular and Intracellular) Microcystins - ADDA by ELISA Analytical Methodology" version 2.2 (November 2015) requires MDLs be calculated annually by each analyst, when a new analyst begins work or whenever a change in analytical performance caused by either a change in instrument hardware or operating conditions. A copy of the MDLs must be maintained as part of the laboratory record maintenance protocol. For any new analyst a copy of the MDLs must be submitted to Ohio EPA's Laboratory Certification Section for review.

<u>3745-89-08, Reporting of analytical results</u>

Comment 98: "Regarding submittal of results, remove the requirement to submit cyanobacteria screening results because this data is for internal utility use and should not be regulated. The description of the reporting method is too vague. As stated, '*All reports required under this rule shall be submitted electronically via a method acceptable to the director.*' We recommend that all required monthly algal toxin data be submitted the same as all other required data, in the Monthly Operating Reports on the e-Biz electronic data reporting system." (John O. Moore, City of Akron)

Response 98: The submittal of cyanobacteria screening results is necessary because they will be used as a screening tool that prompts further testing by Ohio EPA for cyanotoxins via another method. By the effective date of Chapter 3745-90 the reporting of all required data will be submitted using the electronic drinking water reporting system (eDWR) accessed through the eBusiness Center.

Comment 99: "*All detections of microcystins* should be changed to *detections of at least 0.3 µg/L or higher* which is consistent with the current Ohio EPA endorsed method. As newer and better methods become available with very low detection limits, detecting at a very low concentration should not trigger the actions described." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 99: This change is unnecessary. "Detection" is defined in rule 3745-90-01 as equal to or greater than the reporting limit for the analytical method. The reporting limit for microcystins is established in Appendix B of rule 3745-89-03 as 0.3 µg/L.

Comment 100: In regards to paragraph (B)(3), "please state which action level is to be used to trigger these actions. 3745-90-02 contains two action levels." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 100: A notation has been included, identifying the action levels of concern from 3745-90-02 of the OAC.

Comment 101: "Cyanobacteria screening results are required to be reported no later than the end of the next business day if they indicate that there is potential for production of cylindrospermopsin, saxitoxins and anatoxin-a. However, there is no reference on the follow-up actions either by OEPA or the utility. Please include what response actions the OEPA plans to take or require the utility to take. If there are no actions, these results should be reported with the usual MORs. Moreover the word 'potential' is a subjective unscientific term and should be changed to a specific and actionable 'trigger level'. There are also no action levels in the proposed rules for saxitoxins or anatoxin-a so these will be excluded from required monitoring." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 101: Cyanobacteria screening results will trigger a response by Ohio EPA. These actions will be described in the revised HAB strategy.

<u>Business Impact Analysis (BIA)</u>

Comment 102: Question #1, in the first section, the fifth bullet states that "a general plan is required for systems detecting more than 5 micrograms per liter in source water. However, in 3745-90-05(B) it states that systems detection more than 1.6 µg/L are required to submit a general plan." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 102: The BIA has been revised.

Comment 103: Question #1, in the second section, the bullet on rule 3745-89-03 states that "the rule describes the allowable amounts of unacceptable results. I could not find a reference to this in that section of the rule." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 103: Subparagraph (B) of rule 3745-89-03 defines the permitted unacceptable results in regards to required annual proficiency test results and plant control tests. This section had no changes relating to Chapter 3745-90. However, some of the rule language was cleaned up in regards to total trihalomethanes, volatile

organic chemicals, pesticides and other organic chemicals and haloacetic acids (five).

Comment 104: Question #4, the second paragraph discussed "the microcystin method. However, nowhere in the document does it discuss the qPCR method, its shortfalls, the lack laboratory capacity to this testing nor how qPCR is generally not an acceptable testing method due to its inability to detect live organisms nor whether an organism is producing a toxin."

Also in this question, the third paragraph "describes Standard Methods but fails to mention that the analytical methods used in this rule are neither Standard Methods nor ASTM methods." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 104: The BIA has been revised to add discussion of qPCR and note that both qPCR and ELISA are Ohio EPA methodologies (not ASTM or Standard Methods). qPCR will be used as a cyanobacteria screening tool, not as an analytical method to determine microcystins. See response to Comment 66 for more information on the rationale for use of qPCR as a screening tool.

Comment 105: Question #8, the fifth bullet: "By relying solely on the ELISA method in determining when to issue public advisories, the Agency is assuming that all of the microcystin detected is the LR congener, which is the most toxic of the congeners. However in the environment, total microcystin is a mixture of various congeners with lower toxicity than the LR. By assuming all microcystin is LR, the Agency is adding layers of conservatism on top of the already very conservative values to the health advisory levels established by the Ohio EPA."

Also in this question, in the sixth bullet, at the end of the paragraph it "states results of screening *which indicate the potential for production of other cyanotoxin.* However, nowhere in here or the rules has the Agency defined what a potential is and how the monitoring required will be used to ascertain if there is a potential and how realistic of a threat is indicated by monitoring results." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 105: See response to Comment 2.

Cyanobacteria screening results will trigger a response by Ohio EPA based on the presence of genes specific to toxin production. These actions will be described in the revised HAB strategy.

Comment 106: Question #11, "OEPA clearly states that it is implementing USEPA's Health Advisory (HA) level but fails to mention anywhere in the rules that the action levels are based on 10-day exposure HA levels. Moreover, the BIA also states as an example that the Cyanotoxin general plan is performance based. Please

elaborate on the criteria and the flexibility provided to utilities while deriving this conclusion." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 106: The rules have been revised to reference the 10-day U.S. EPA health advisory level. The performance standard for the cyanotoxin general plan is that microcystins will not be detected in finished water. Public water systems have many different approaches to achieve this end point, including reservoir management, avoidance strategies such as emergency interconnections and treatment.

Comment 107: Question #14, "We believe that the agency has failed to provide adequate explanation for *adverse impact to business* and does not include all elements in the adverse impact assessment that would affect the cost of compliance. The cost of compliance is severely underreported. For example, the agency states the total maximum cost of compliance with Chapters 3745-90-05 and 3745-90-06 as only about $150,000 for systems serving 100,000 or more people. It is unclear whether these are annual costs are otherwise. The agency should seek stakeholder input to consider all aspects of compliance in developing true cost impact to justify the regulation. Specifically, the agency has failed to take into account the impact to treatment and distribution system costs including restoration of the system in case of a 'do not use advisory.' The agency should revise all costs including for Chapters 3745-90-05 and 3745-90-06. OEPA is well aware from recent incidents where the cost of cyanotoxin mitigation exceeded millions of dollars including loss of public confidence and impact to local economy." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 107: Ohio EPA provided the draft BIA (along with the rules) for interested party review in order to seek stakeholder input on both the rules and the BIA. Ohio EPA has revised the BIA to include information provided by public water systems on the cost of compliance with these rules.

<u>Policy on Limited Distribution of Public Notice (WQ-06-002)</u>

Comment 108: "The policy only applies to *violation* of OAC Chapter 3745-81. Exceedance of an *Action Level* for cyanotoxins is not in itself a violation. Please amend the policy to include exceedance of *Action Level* in the proposed OAC Chapter 3745-90." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 108: Agreed; this revision has been made.

Comment 109: In section III, #2 "hydraulic isolation areas of a distribution system may not be able to be designated well in advance and included in the emergency contingency plan. Especially in bigger and more complex systems, hydraulic isolation is dependent upon the specific system operational characteristics at the time. Instead of being identified in the contingency plan, the contingency plan should include the criteria to evaluate to identify these areas and describe

how the areas would be identified in any particular water emergency. This could include hydraulic modeling, water quality monitoring data, pump station operational data, tank operational data, valve position data, water demand, etc."

Response 109: Agreed; this revision has been made.

Comment 110: In section III, #3 and #4, "email should be added as an acceptable method of communication." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 110: Agreed; this revision has been made.

Ohio EPA Total (Extracellular and Intracellular) Microcystins – ADDA by ELISA Analytical Methodology

Comment 111: "There is no provision for the collection of extracellular toxin or mention of how the sample must be treated in the method. Although the draft HAB rules apply only to total toxins, knowledge of intracellular vs. extracellular toxin is valuable when determining treatment strategy. Please provide guidance for conducting extracellular analyses." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 111: The rule does not require the analysis or reporting of extracellular microcystins. However, the Ohio EPA's Division of Environmental Services has a method for determining extracellular microcystins. This document is available upon request.

Comment 112: "To avoid the loss of a very expensive run due to a single high standard %CV (i.e. >15%), allow that standard to be eliminated, assuming it was not the lowest or highest standard. This will improve the R squared result and provide more accurate results without requiring a rerun."

"A low R squared value is usually due to a problem with one of the standards. Consider allowing the dropping of the standard in question, assuming it was not the lowest or highest standard. If the R squared value becomes acceptable, allow the results to be considered as passing QC." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 112: Good laboratory practice does not allow for curve manipulation. A calibration curve must ensure the calibration range includes the expected sample concentrations. If a sample result exceeds the calibration range then the sample must be diluted and reanalyzed with in the calibration range. The Ohio EPA's Laboratory Certification Section does not allow for any more than the highest point in a calibration curve to be dropped. When using the ELISA method this would apply to both replicates of the highest standard.

Comment 113: "Abraxis allows multiple 96 well sample plates to be analyzed based on standards run on only one of the plates. There is no mention of this in the method. Please clarify whether we must reserve 18 wells for standards and QC's on each plate of 96 wells, or is it acceptable to determine results based on a previous plate that had good QC, and under what criteria." (Jeff Swertfeger, Greater Cincinnati Water Works)

Response 113: The manufacturer instructions for Abraxis state that values for previously determined standards cannot be used. The Ohio EPA Total (Extracellular and Intracellular) Microcystins – ADDA by ELISA method requires all calibration standards and quality control with each analytical batch.

End of Response to Comments