# Division of Drinking and Ground Waters
# Response to Comments

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

3745-90-01, Harmful algal blooms – definitions
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3745-89-08, Reporting of analytical techniques

**Agency Contact for this Package**

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Ohio EPA issued public notice and requested comments for the period of January 19, 2016 to February 24, 2016 on proposed rules in the Ohio Administrative Code (OAC). This document summarizes the comments and questions received during the comment period.

Ohio EPA reviewed and considered all comments received during the 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:** "With an informational webinar held more than half way through the 30-day comment period, public water systems were left with less than two weeks to provide input. Nonetheless, we encourage you to review and re-examine the letters and comments already submitted." (Doug Wagner, Toledo Metropolitan Area Council of Governments Public Water Supply Committee or TMACOG-PWS)

**Response 1:** The rulemaking 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 rules. We apologize for any inconvenience this accelerated rulemaking may have caused.

**Comment 2:** **The following are general comments on the science behind these rules:**
"We remain concerned with Ohio EPA trying to conduct regulatory functions normally done by USEPA in a prescribed rule making procedure. Proper epidemiology is still categorically deficient and is being replaced with literature review. Analytical methods are still being developed and have not been evaluated properly to be escalated to the regulatory role Ohio EPA is forcing."

"Elevating a federal Health Advisory Level to the significance of an Acute MCL without proper, industry-accepted epidemiology is not appropriate regulation." (Margaret L. Rodgers, City of Cleveland)

"We strongly believe regulations must be able to demonstrate a meaningful opportunity to reduce risk, be based on peer-reviewed science, and consider affordability. We also believe state regulations should be 'synced' with federal regulations so as not to burden utilities with redundant, overlapping, or worse conflicting requirements." (Thomas Schwing, Aqua Ohio)

"Akron fully supports responsible regulation of all aspects of a drinking water utility's operation to ensure the production and delivery of safe drinking water. Akron is as concerned about harmful algal bloom toxins as Ohio EPA is. Akron also supports data collection and scientific research into the threats posed by algal toxins in finished drinking water. However, Akron cannot support, and objects to the Proposed Rules because the Proposed Rules are premature and are not based upon sufficient scientific evidence. In short, Akron continues to believe that these Proposed Rules will result in unnecessary deterioration of confidence in public water supplies because they are based upon methods and data which are not yet scientifically proven to be protective of public health or the environment, and they are not cost effective."

"First, total Microcystins in drinking water are not currently regulated with a standard, regulation or guideline under the federal Safe Drinking Water Act. Instead, Ohio EPA is relying upon the U.S. EPA *Drinking Water Health Advisory for Cyanobacterial Microcystins Toxins*, June 2015, to establish action levels in the Proposed Rules. The levels in this Health Advisory are based upon limited research and data. Moreover, 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.' The use of such a health advisory is clearly not an appropriate basis of establishing enforceable regulatory standards. In fact, by overreacting and setting unsubstantiated algal toxin action levels based on limited science and research, the Proposed Rules

could cause utilities to compromise compliance with other U.S. EPA regulatory limits."

"U.S. EPA's latest published list of all standards and health advisories is from 2012 (*2012 Edition of Drinking Standards and Health Advisories*, EPA 822-S-12-001, April 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. It follows that the mere issuance of a health advisory by U.S. EPA is not a sufficient basis for establishing an enforceable regulatory standard. Akron requests identification of other states which Ohio EPA says already use U.S. EPA health advisory levels as enforceable limits."

"Second, the regulatory process followed by U.S. EPA involves developing data that is gathered and evaluated in accordance with scientific protocols. Notably, Microcystins are slated to be tested on the next UCMR 4. Surely, recommendations for monitoring, treatment, testing, reporting, health standards, and notifying the public will change as part of this ongoing regulatory process. Moreover, the push for additional testing at this level underscores that there is not yet enough research data to conclude that Microcystin toxins are harmful at the levels set by Ohio EPA. Therefore, Akron believes that it would be prudent and appropriate for Ohio EPA to delay its rule making effort until U.S. EPA implements the foregoing regulatory process. In that way, Ohio EPA and the drinking water utilities will have the benefit of regulatory standards that are based upon adequate research and that identify the appropriate treatment technologies, standardized laboratory methods, and public notification requirements."

"While U.S. EPA is implementing its regulatory process, 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 of specific cyanotoxins. The establishment of protocols, outside of the formal ruling process, will allow Ohio EPA and drinking water utilities to adapt to the continued changes and to take advantage of advancement in treatment technologies."

"The establishment of such protocols, outside of the formal regulatory process, is consistent with the requirements of 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."

"Akron believes that the Proposed Rules are premature, and Akron urges Ohio EPA to place the proposed rules on hold until U.S. EPA completes its investigation of cyanotoxins and develops standards under the federal Safe

Drinking Water Act. In the interim period, Akron further recommends the collaborative establishment of protocols for monitoring, testing and reporting of specific cyanotoxins so that drinking water utilities can adapt to the continued changes that will result from U.S. EPA's ongoing regulatory process." (John O. Moore, City of Akron)

**Response 2:** The occurrence of harmful algal blooms in Lake Erie, the Ohio River and dozens of inland water bodies used as a source of public drinking water, has driven the need for the State of Ohio to take a more proactive approach to addressing this threat to public health. 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, including the underlying research on which it is based, underwent two rounds of expert peer review. As with many regulated contaminants, Ohio EPA recognizes there are some toxicological data gaps, including those that could drive the threshold lower, but this is currently the best available science regarding health effects of microcystins. Ohio EPA does not anticipate modifications to U.S. EPA's health advisory for microcystins or development of a microcystins MCL for at least several years. Given the expectations under Ohio Revised Code or R.C. 3745.50, Ohio EPA cannot wait for the results of the fourth Unregulated Contaminant Monitoring Rule (UCMR 4) and the several additional years for adopting federal regulations. 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 has not surveyed all states to determine which utilize health advisories as enforceable limits. During HAB-related state conference calls, several states have indicated they utilize health advisories in this way. For example, Pennsylvania uses U.S. EPA's, one-day and ten-day health advisory levels to determine at what level a contaminant exhibits acute health effects. When a water supplier exceeds these levels, it becomes a "situation with significant potential to have serious adverse effects on human health," which requires one-hour reporting to DEP and issuance of Tier 1 PN." (E-mail communication from Lisa Daniels, PA Department of Environmental Protection or DEP, 12/7/15).

The State of Ohio has continued to refine its preparation and response to the increasing occurrence of HABs. The state currently has statutory authority to act if algal toxins are detected in finished water and has previously done so in 2013 and 2014 under the following:

- Ohio Revised Code § 6109.12: Public Water System Analysis.
- Ohio Administrative Code (OAC) rule 3745-81-32: Public Notification.
- Ohio EPA policy WQ-07-002: Tier 1 Public Notification Requirements (rule requirements are legally enforceable).

The new rules were necessary to ensure the monitoring and implementation protocols outlined in the aforementioned Ohio Revised Code sections are conducted to protect public health. The rules establish 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. While Ohio EPA appreciates the voluntary HAB monitoring that several water supplies have conducted in the past, rules are necessary to ensure all water systems that utilize surface water are monitoring for and appropriately responding to cyanotoxins in their source water.

**Comment 3:** **The following are comments on the costs of the rules:**
"…it bears repeating that the Proposed Rules are likely to heap a huge burden on communities like Akron in the event of an issuance of a 'do not drink' advisory stemming from Microcystins levels exceeding the 0.3 µg/L level, which would be directed at young, compromised and elderly populations, but would ultimately impact the community as a whole. As mentioned in Akron's October 23, 2015 letter, there is the substantial financial burden 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. In other words, such an order could cost Akron between $29 million and $62 million *per day*." (John O. Moore, City of Akron)

**Response 3:** Ohio EPA believes the costs of these rules are justified and necessary to successfully achieve the directives established in R.C. 3745.50, to protect public health, and to address public expectations that public water systems routinely monitor and treat for cyanotoxins. Ohio EPA takes the issue of loss of public confidence in drinking water 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 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 to incentivize water systems to actively addressing HAB issues through source water protection, reservoir management, avoidance strategies and demonstrated treatment in order to avoid exceedances which would require a public notice.

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 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 offered $100 million in targeted zero-to low-interest loans for infrastructure improvements. Ohio EPA anticipates making additional funds available for these activities.

As mentioned in Response #2 above, Ohio EPA has existing authority to respond to algal toxins in drinking water. "Do Not Drink" advisories due to algal toxins in finished water were previously issued in 2013 and 2014. Regardless of whether or not the new rules are adopted, Ohio EPA will continue to respond to algal toxins in drinking water under existing authorities, including potential issuance of "Do Not Drink" advisories if warranted. However, the new rules provide a

clear response, reporting and prevention framework for both the agency and the public water systems moving forward. This gives certainty and therefore increased confidence and quality.

**Comment 4:** "In the December 1, 2015 CSI-Ohio Business Impact Analysis, Ohio EPA stated that funding had been made available to the regulated community to assist in off-setting the impact costs of the proposed regulations. Will Ohio EPA continue to make grant funds available to impacted PWS for the actual implementation of the new regulations?" (Thomas Schwing, Aqua Ohio)

**Response 4:** Ohio EPA has made $1 million dollars in grants available to public water systems (PWSs) to establish their own analytical capabilities and offered $100 million in targeted funds zero-to low-interest loans for infrastructure improvements. Ohio EPA anticipates making additional funds available for these activities starting on July 1, 2016 through the Water Supply Revolving Loan Account or WSRLA loan program. Information about both funding opportunities will be provided to public water systems**.**

In addition, Ohio EPA is conducting and absorbing the costs of approximately 50 percent of the analyses required during the first year of these rules. We are currently working with public water systems on mechanisms to substantially reduce the costs of shipping samples to Ohio EPA.

**Comment 5:** "While the agency is taking important steps here to protect the public, the proposed rule is not perfect. The OEC and ELPC are concerned that the rule will allow for substantial delays in public notification. These delays could represent a very serious threat to public health. Under a worst case scenario, it could take 27 days between microcystins appearing in finished drinking water and a do not drink/do not use notice going out to the public. A hypothetical worst case scenario is illustrated in the table below."

| Day | Event or Action | OAC Section |
|---|---|---|
| 1 | microcystins present in finished drinking water | |
| 14 | bi-weekly sample collected (November - April) | 3745-90-03(A)(2)(b)(i) |
| 19 | (a Friday) sample is analyzed | 3745-90-04(C)(2) |
| 22 | results are reported at end of business day | 3745-89-08(B)(3) |
| 23 | resample collected | 3745-90-03(A)(4)(a) |
| 24 | resample analyzed | 3745-90-03(A)(4)(a) |
| 24 | repeat sample collected | 3745-90-03(A)(4)(b) |
| 25 | resample reported | 3745-89-08(B)(3) |
| 25 | repeat sample analyzed | 3745-90-03(A)(4)(b) |
| 26 | repeat sample reported | 3745-89-08(B)(3) |
| 27 | Tier 1 public notice issued by PWS | 3745-90-06(A)(1)(a); 3745-81-32(B)(3)(a) |

"A 27-day delay (and, conceivably, one much shorter) would be completely unacceptable from a public health standpoint. A delay of this or similar length would greatly exceed the 10-day exposure period contemplated in the rule. Moreover, the 10-day period may well prove a perfectly useless metric where contamination levels substantially exceed 0.3 and 1.6 micrograms per liter. As Ohio EPA notes in its response to comments, the 10-day exposure principle 'cannot be interpreted to mean that individuals can tolerate any amount above [those] level[s] for 10 days.' [3]"

"The public notification timeline needs to be shortened. Perhaps the most effective way to achieve more rapid public notification is to require at least weekly testing for microcystins rather than bi-weekly during the months of November through April. See 3745-90-03(A)(2)(b)(i). This would also be in accord with the agency's original proposal. The agency should also require 24 hour analysis of all samples taken, rather than the 5-day timeframe that applies to many samples. See proposed OAC 3745-90-04(C)(2)."

"We also encourage the agency to increase the 3 times per week sampling requirement to daily sampling where microcystins exceed 5 micrograms per liter at the raw water sampling point. See proposed OAC 3745-90-03(A)(2)(c)."

"There is a technical flaw in proposed OAC 3745-90-03(A)(2)(d). This rule requires daily monitoring where microcystins are detected in finished water and/or distribution points. The rule also specifies two avenues through which monitoring may return to 3 times per week.[4] The first avenue contains the flaw, and states:

> Routine monitoring may resume in accordance with paragraphs (A)(2)(a) and (A)(2)(b) of this rule if the two most recent consecutive daily samples from the raw water sampling point are equal to or less than five ug/L[.]"

"OAC 3745-90-03(A)(2)(d). The problem with the above language lies in the fact that it fails to account for scenarios in which raw water concentrations are below 5 micrograms per liter, but where finished water concentrations are nonetheless above specified action level(s). It would clearly be absurd to allow PWSs to reduce monitoring frequency under scenarios of this nature, and such a result was clearly not intended by the agency. The language in question should therefore be modified to prohibit reductions from daily sampling frequency unless and until microcystins are absent from finished water and the distribution system."

"The agency should also tighten the proposed definition of 'action level' to specify that regulated parties are not permitted to round analysis results down to avoid exceeding action levels. Currently, there is no definition for 'exceed' or 'exceedance' as regards action levels. See proposed OAC 3745-90-01(A) (defining 'Action level'). Consequently, it is not entirely clear whether hypothetical results of 0.31 or 0.301 micrograms per liter, etc., would qualify as exceeding the applicable action level. In theory, a regulated party or the agency could even go so far as to interpret the rule to mean that detections of 0.4 or

1.7 micrograms per liter, respectively, are required before an exceedance results. We encourage the agency to more clearly specify that any detection above the action levels, regardless of decimal place, constitutes an exceedance. We also encourage the agency to specify that the 'rounding down' of decimal places to meet action levels is not permitted." (Nathan Johnson, Ohio Environmental Council or OEC; Madeline Fleisher, Environmental Law & Policy Center or ELPC)

[3] OEPA, Public Water System (PWS) Harmful Algal Bloom (HAB) Rules Response to Comments, December 2015, page 14.

[4] While we think daily monitoring rather than 3-times-weekly is appropriate where raw water exceeds 5 micrograms per liter, we offer the following observations in the event the agency decides to retain the 3-times-weekly schedule.

**Response 5:** 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 rule 3745-90-06 (A)(1)(b) of the Ohio Administrative Code or OAC). Further, monitoring is increased to 3 times per week if source conditions degrade (> 5 µg/L microcystins).

Past monitoring data has shown that microcystins detections are most common from May through October, with a peak in August. This can be attributed in part due to temperature limitations associated with Microcystis, which is a commonly occurring genera in Ohio. Since other cyanobacteria genera are not as temperature dependent and microcystins have been detected at some water systems year-round, baseline monitoring is needed throughout the entire year. Water systems will not be able to go on the reduced November through April monitoring schedule until they have had two consecutive weeks without microcystins detections in both their raw and finished water. In addition, a raw water detection in the November through April time period will trigger immediate finished water sampling followed by weekly monitoring until toxins are no longer detected for two consecutive weeks.

If there is a detection of microcystins in finished water, the rules [OAC 3745-09-03(2)(d)(i)] will require daily analysis to continue until there are two consecutive daily samples below detection.

The timeframe for compliance sampling is based on the holding time established in the analytical method. Since the U.S. EPA health advisory for microcystins is based on short term (up to 10 days) exposure, a five day holding time for routine sampling is appropriate. If microcystins are detected in finished water, analysis timeframes for daily samples are decreased to 24 hours.

The approach used for determining when an action level is exceeded is consistent with other Safe Drinking Water Act regulatory standards. 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. This is based on federal guidance on rounding to a significant digit.

The raw water monitoring frequency outlined in this rule goes beyond most public water system monitoring requirements, in part due to the transient nature of harmful algal blooms and the need for public water systems to respond rapidly in order to prevent 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.

**Comment 6:** "The proposed rules require bi-weekly cyanotoxin sampling (in addition to microcystins sampling). Cyanotoxin sampling should be increased to at least weekly, so the agency can ensure more timely detection of saxitoxins, cylindrospermopsin, and anatoxin-a. Cyanotoxin analysis should also be on a timeline faster than 7 days."

"Moreover, the agency should require public notification when these three cyanotoxins are present in drinking water. The agency already has health advisory levels for all three in its 2015 HAB Response Strategy document.[5] It should use them."

| Drinking Water Threshold | Microcystins** (µg/L) | Anatoxin-a (µg/L) | Cylindrospermopsin (µg/L) | Saxitoxins** (µg/L) |
|---|---|---|---|---|
| Do Not Drink – children 6 and sensitive populations*** | 0.3 | 20 | 0.7 | 0.2 |
| Do Not Drink – children 6 and older and adults | 1.6 | 20 | 3.0 | 0.2 |
| Do Not Use* | 20 | 300 | 20 | 3 |

(Health Advisory Level table taken from OEPA's 2015 HAB Response Strategy document, p. 14)

"We urge the agency to mandate Tier I public notification for the presence of anatoxin-a, cylindrospermopsin, and saxitoxins in finished drinking water at the above-enumerated concentrations. The public deserves to know in a timely fashion when the safety of its drinking water is legitimately threatened. Requiring notification of these toxins will reassure the public that, absent an active advisory, their water is safe to drink." (Nathan Johnson, OEC; Madeline Fleisher, ELPC)

[5] PWS HAB Response Strategy 2015, page 14 available at: http://epa.ohio.gov/ddagw/HAB.aspx.

**Response 6:** 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 Public Water System 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.

Ohio EPA will continue to recommend that public water systems issue Tier 1 PNs for other cyanotoxins if detected in finished water, per the State of Ohio Public Water System HAB Response Strategy. Ohio EPA's director also maintains the authority to issue a PN for one of the other cyanotoxins, if they are detected in finished water at concentrations that pose a threat to human health and the water system does not issue a PN voluntarily.

**Comment 7:** "We appreciate the agency's proposed rule that requires the reporting of microcystins information in Consumer Confidence Reports (CCRs). See proposed OAC 3745-90-06(B). We suggest, however, that the agency also require PWSs to report the number of days for which microcystins action levels were exceeded. This information is material to public health and public confidence, and should be made available to the public."

"We also urge the agency to require CCR reporting of exceedances for the cyanotoxins cylindrospermopsin, anatoxin-a, and saxitoxins (for which we urge the agency to require monitoring and public notification, supra)."

"In addition, we urge the agency to post all reported microcystins, cylindrospermopsin, anatoxin-a, and saxitoxins samples to the Ohio EPA website. At the very least, the agency should post all samples demonstrating action level exceedances to the agency website. The agency currently posts agency-sampled results to its website and has adopted this practice in its policies.[6] Ohio EPA should extend this practice to PWS-sampled results (irrespective of concurrence) and should enshrine the practice in rule as mandatory." (Nathan Johnson, OEC; Madeline Fleisher, ELPC)

**Response 7:** Providing specific instructions on how to describe the action level exceedances is more appropriate in the more detailed Consumer Confidence Report Template and Instruction Guide Instruction Guide on the Ohio EPA website at http://epa.ohio.gov/ddagw/pws.aspx, and in Chapter 3745-96 of the Administrative Code. Ohio EPA understands that the frequency and timing of microcystin detections over the action level will be unique to each water system. Some may have a single exceedance to report, some may have one event over several days to report, and others may have periodic isolated exceedances. Each PWS will have to report in the table of detected contaminants or in a narrative, a clear description of what occurred.

Included in OAC 3745-90-06 is a list of the minimum information that the PWS must supply regarding microcystin detections above the action level in the CCR. Details and examples on how to include the information in the CCR are provided in the CCR Template and Instruction and Template Guide and in Chapter 3745-96 of the Administrative Code. The CCR Instruction Guide is

updated every year and will include a discussion of how to display HAB action level exceedances in the 2016 update. When sample results are displayed in the detected contaminant tables there is a column for "Year Sampled" which the PWS can also use to list a specific date or date range if that is more appropriate.

In regards to reporting the results of cylindrospermopsin, anatoxin-a, and saxitoxins analysis in the CCR, only regulated contaminants, radon, and unregulated contaminants that have monitoring requirements are to be reported in the CCR. Since cylindrospermopsin, anatoxin-a, and saxitoxins do not fall into one of these categories they are not included in the CCR requirements of 3745-90-06.

Ohio EPA will continue to post all cyanotoxin raw and finished water sampling data to Ohio EPA's website. This includes microcystins, saxitoxins, cylindrospermopsin, and anatoxin-a data.

**3745-90-01, Harmful algal blooms – definitions**

**Comment 8:** "Clarify other types of phytoplankton identification which would be acceptable to the director." (John O. Moore, City of Akron)

**Response 8:** At this point only molecular methods are being considered, but this caveat was included in the rule in case other methods are established. For example, digital microscopy methods are improving (FLOWCAM, etc.) that may make quick, efficient and reproducible phytoplankton identification a possible method in the future.

**3745-90-03, Harmful algal blooms – monitoring**

**Comment 9:** "Raw water monitoring should not be included in the Proposed Rules. The utilities should monitor their source waters as they choose, and there should only be enforceable violations on finished water leaving the treatment facility. Under the Proposed Rules, there are two solutions for exceedances in raw water:

- if toxins are detected at any time in raw water after the rules go into effect, or there was a toxin detection in raw water between July 16, 2015 and the date of the Proposed Rules are enacted, the utility is required to develop, submit and have approved an optimization protocol within 30 days.
- if toxins are detected above 1.6 micrograms/L in the raw more than one time in a 12 month period, a utility has 120 days to create and submit a cyanotoxin general plan."

"These requirements are costly and time-consuming. If a utility is already struggling with cyanotoxins the pressure of having to prepare and submit a plan within 30 days is unreasonable. Most of these plans already exist in EAPs or EOPs, which should be in Ohio EPA's possession. If such plans are not sufficient,

then Ohio EPA should work directly with each utility to correct the deficiencies. Further, a cyanotoxin general plan should not create a tier 2 notification if it is not completed within the required timeframe. These examples show just how time-consuming the sampling and reporting of raw water can be, and how unreasonable the burden is for communities like Akron." (John O. Moore, City of Akron)

**Response 9:** Raw water monitoring and treatment optimization requirements are intended to prevent finished water detections and the corresponding high financial and public confidence costs. 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. Ohio EPA considers routine monitoring to be essential, as HABs are not always visually apparent and an approach based on visual observations has limitations.

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, which will also alleviate some of the financial burden.

The requirements for the treatment optimization protocol and the General Plan are different in both response timeframes and approval. Upon triggering conditions in OAC 3745-90-05(A), a treatment optimization must be submitted within 30 days based on conditions outlined in OAC 3745-90-05(A). Upon triggering conditions in OAC 3745-90-05(B), a General Plan must be submitted within 120 days to the Director for approval in accordance with OAC 3745-91-02(C).

The treatment optimization protocols 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. Ohio EPA staff has previously provided guidance, training and technical assistance to assists public water systems to develop treatment protocols. A number of systems already have treatment protocols in place and any previous efforts to document and optimize treatment will be helpful in fulfilling these requirements. Ohio EPA will provide comment but will not formally approve these protocols.

Ohio EPA is drafting additional 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.

Failure to submit a General Plan is considered a Tier 2 notification for failure to address treatment and it is a treatment technique violation. Classification as a Tier 2 PN is consistent with how Ohio handles the surface water treatment rule.

**Comment 10:** "Eliminate all wording regarding sampling of raw water. Only the tap water should be regulated. Concentrations of algal toxins in the raw water can be misleading to the public. Raw water numbers currently have no comparative value to the finish water due to the fact that the algal toxins may be removed by the treatment system." (John O. Moore, City of Akron)

**Response 10:** See Response #9.

**Comment 11:** "Water standards should be scientifically sound. Microcystin production in Lake Erie occurs during warm weather. Based on 5 – 6 years of testing, PWC members have data indicating 'non-detect' results during the off-season. We therefore recommend that after having two consecutive non-detect readings in October, testing should be once a month until June 1."

"Additional testing during a known non-detect period would reduce the ability and resources available to perform other duties such as preventative maintenance. It is important to utilize resources in as productive a way possible." (Doug Wagner, TMACOG-PWS)

**Response 11:** Year-round sampling is necessary for public health protection and 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 year round. The majority of sampling to date 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 12:** "If the OEPA rules result in an increase funding of testing during a traditional non-detect period, we recommend providing funds during those off-season months. These funds are often in excess of $10,000, and we appreciate Ohio EPA's efforts to help by providing grant funds and other assistance." (Doug Wagner, TMACOG-PWS)

**Response 12:** To provide assistance and relief for testing costs, Ohio EPA has made $1 million dollars in grants available to public water systems to establish their own analytical capabilities. In addition, Ohio EPA is conducting and absorbing the costs of approximately 50 percent of the analyses required during the first year of these rules. We are currently working with public water systems on mechanisms to substantially reduce the costs of shipping samples to Ohio EPA

**Comment 13:** "If the OEPA implements more frequent testing during the off-season, the PWC recommends a pilot period of 1 year, and if 'non-detect' occurs in 6 consecutive months, rules would be modified to reduce off-season testing frequency." (Doug Wagner, TMACOG-PWS)

**Response 13:** Following the first year, Ohio EPA will fully evaluate the results and occurrence of algal toxins and determine if modifications to the testing requirements are warranted. 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 14:** "Ohio Administrative Code (OAC) 3745-90-03(A)(3) appears to now permit commonly accepted science-based tools to be considered, albeit only to change monitoring requirements at the discretion of the director. The 'discretion of the director' is extremely vague. Ohio EPA must provide more clarification on when this type of information can be use. Specific monitoring methods are cited, but equally important operational tools appear to be excluded (e.g., pH, chlorine demand, and filter run times). Please explain why Ohio EPA is not using these important operational tools." (Margaret L. Rodgers, City of Cleveland)

**Response 14:** The factors the director may consider to revise monitoring frequencies are provided as examples. Ohio EPA did not want to limit the factors that may be considered. The variability in source waters and treatment capabilities makes listing all factors impractical. Specific treatment capabilities as described in general plans may also be considered in establishing monitoring frequencies.

**Comment 15:** "If a surface water treatment plant routinely proves capable of removing or destroying cyanotoxins, then the plant should be eligible for reduced monitoring without going through an entire year of monitoring. Design and operational criteria for PAC application, sedimentation, oxidation, and chlorine contact time should be used to determine reduced monitoring. This is particularly relevant when historical raw water algal toxin concentrations are negligible. Lake Erie has seen two of the worst algal bloom seasons in history, including last year, and there were no Lake Erie water use advisories issued. Ohio EPA must recognize the treatability of cyanotoxins, particularly for Lake Erie water plants." (Margaret L. Rodgers, City of Cleveland)

**Response 15:** Treatment capability can be a consideration for reduced monitoring.

**<u>3745-90-04, Harmful algal blooms – analytical methods and reporting</u>**

**Comment 16:** "Clarify acceptable screening methods other than qPCR. Screening requirements under this provision should not be required to be reported as analytical data and should be treated as a tier 3 violation under 3745-90-04(E)." (John O. Moore, City of Akron)

**Response 16:** 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. Screening for cyanobacteria will be required by rule and therefore is subject to a tier 3 public notice. OAC Rule 3745-81-32(D) requires the owner or operator of a PWS to provide public notice for violation of monitoring and testing procedure requirements.

**Comment 17:** "NEORSD is concerned that there is only one laboratory (Ohio EPA's DES Laboratory) performing the validation of Ohio EPA's proposed new method for screening samples for microcystins and various toxic genes using qPCR. Typically, when a new method is being developed or validated there is at least one other laboratory used as a quality control laboratory to verify the results obtained during the validation process. The qPCR method is a new method that has not undergone a formal QA/QC or validation process similar to the validation process used when new ASTM or U.S. EPA methods are developed. When the U.S. EPA approves a new analytical method, numerous laboratories are typically involved in the validation of the new method. NEORSD recommends that Ohio EPA consider using other laboratories to assist with

qPCR method validation." (Julius Ciaccia, Northeast Ohio Regional Sewer District or NEORSD)

**Response 17:** Ohio EPA plans to involve at least one independent laboratory in method validation study. Ohio EPA is also working with U.S. EPA, USGS, and NOAA-Great Lakes Environmental Research Laboratory on method development and ongoing method validation.

**Comment 18:** "With respect to the language in section 3745-90-04, NEORSD requests that Ohio EPA clarify how the director will determine if there is sufficient certified laboratory capacity for cyanobacteria screening. Please provide the criteria that the director will use to determine sufficiency of laboratory capacity." (Julius Ciaccia, NEORSD)

**Response 18:** Once the analytical method has been validated, the drinking water laboratory certification staff will begin accepting applications and providing on-site inspections to determine certification for the cyanobacteria screening method. Once laboratories are granted certification, Ohio EPA anticipates there will be sufficient laboratory capacity beyond Ohio EPA.

**Comment 19:** "NEORSD requests that Ohio EPA clarify its rationale for limiting cyanobacteria screening to Ohio EPA's DES laboratory for at least one year after the effective date of the rule. There is at least one other laboratory in the State of Ohio that has ability, expertise and capacity to perform the qPCR screening method and there may be other laboratories that currently have or that will soon have this ability, expertise and capacity. NEORSD requests that Ohio EPA consider revising the Draft Rule to allow laboratories to become certified and begin performing this screening upon the effective date of the Draft Rule." (Julius Ciaccia, NEORSD)

**Response 19** The rules require Ohio EPA to perform the analysis for at least one year or until adequate laboratory capacity is established to provide public water systems a clearer timeline of when they may have to assume analytical costs.

**Comment 20:** "The use of the qPCR method as a screening tool is still an unreliable test method that has not had appropriate opportunity for proper evaluation and critique. Just because the genes might be present does not mean live, toxin-producing algae are present in source water." (Margaret L. Rodgers, City of Cleveland)

"…the December 2015 Response #2, Ohio EPA acknowledges that '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.' However, in several other December 2015 comment responses, Ohio EPA acknowledges the primary purpose for the collection and use of the qPCR data will be to direct additional monitoring. It

appears that the regulation for PWS to provide qPCR samples is for research to determine if 'the qPCR data is shown to have a strong correlation with microcystins detections' (Response 37). qPCR should not be a requirement of the regulated PWs." (Thomas Schwing, Aqua Ohio)

**Response 20:** Ohio EPA agrees that "just because the genes might be present does not mean live, toxin-producing algae are present in source water." The primary goal of qPCR screening is to direct additional monitoring and analysis for other cyanotoxins by Ohio EPA to be protective of human health. An additional potential benefit could be to reduce microcystins monitoring in the future, if a strong correlation is found between microcystins production and the microcystins gene.

**Comment 21:** "The economics of qPCR shipping materials, labor costs, and sample materials will not be significant for Cleveland Water. Costs associated with the ELISA-ADDA equipment and labor are not able to be estimated, but are anticipated to be substantial and constitute yet another unfunded mandate. Additionally, staff time involved with qPCR and overly-conservative, unnecessary time involved with ELISA-ADDA analyses takes away from other critical laboratory functions. We request the State of Ohio pay for all qPCR shipping and material costs since this information is being gathered for Ohio EPA's benefit, and we see no benefit for Cleveland Water customers." (Margaret L. Rodgers, City of Cleveland)

**Response 21:** Ohio EPA will provide the qPCR sampling containers and analysis at no cost. Ohio EPA is currently working with public water systems to establish mechanisms to reduce the costs of shipping, but sample collection and shipping costs will be the responsibility of the public water system.

**Comment 22:** "The ELISA test method, originally intended as a presence-absence test, continues being the only analytical method accepted by Ohio EPA. It is known the ELISA method has a positive bias and difficulties with the quality control reinforces this test should be nothing more than a presence-absence test. Until a more reliable test method is developed, based on sound science and proper scrutiny by the scientific community, we recommend Ohio EPA cease trying to use this method as a quantification tool for compliance."

"More robust, USEPA accepted test methods, such as HPLC-PDA and LC MS/MS, are available and should be considered by Ohio EPA, particularly for finished water testing. If these methods don't satisfy Ohio EPA goals, then Cleveland Water believes the State should postpone the proposed HAB rules as a regulatory compliance program until the proper science is available." (Margaret L. Rodgers, City of Cleveland)

"A primary issue is the proposed use of the ELISA test method for monitoring and determining the action level response trigger to alleged microcystins presence in the source and/or finished water samples. Specifically, ELISA testing only examines for the possible presence of microcystins and can have variability

in testing results. Further, ELISA testing does not distinguish the microcystin variants, which are known to have different levels of toxicity. Other testing methods, such as liquid chromatography/mass spectrometry, have the capability of identifying specific variants. Accordingly, we are concerned that the use of ELISA testing is overly conservative and false positives would result in higher sampling, operational, and laboratory costs necessary to protect the public."

"As you are no doubt aware, the US Environmental Protection Agency (USEPA) has proposed to include HAB testing as part of their national regulatory program including the use of the ELISA method in the next Unregulated Contaminant Monitoring Rule (UCMR) round (UCMR4)."

"The American Water Works Association (AWWA) in a February 9, 2016 letter to the USEPA (attached) raises the issue of reliability – especially at low concentrations near the Minimum Reporting Level – and interferences with the ELISA test method's proposed use. The Water Research Foundation recently sought proposals evaluating the performance of methods used in the analysis of cyanotoxins. This future project serves to underscore the research nature and many unresolved issues of cyanotoxin analysis in water. Ohio EPA is embarking in an expensive and quite possibly, premature program, exclusively relying on the adequacy of the ELISA method when clearly it is not nationally recognized as ready for such. Simply put, the ELISA method is 'not ready for prime time'."

"It also should be noted, that once the methodologies do reach a point of acceptance for the UCMR4 program, Ohio utilities *will be* required to participate in the development of the national occurrence database using the then EPA certified methodologies, thus dooming Ohio utilities to even further expenditures for what is essentially a redundant undertaking, one by Ohio EPA, and one by USEPA." (Thomas Schwing, Aqua Ohio)

**Response 22:** 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 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. The ELISA MC-ADDA kit is U.S. EPA ETV certified. Validation is part of the ETV certification process. In addition, U.S. Geological Survey 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. U.S. EPA has also included ELISA MC-ADDA as a monitoring tool for UCMR 4.

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.

**Comment 23:** "Cleveland Water does not see the value of continuing the freeze-thaw sequence of the ELISA-ADDA test methodology for reasons stated in our October 23, 2015 comment letter. Unless a public water system intentionally destroys the cell walls as a treatment strategy, the required monitoring should only include extracellular toxin. This is the only realistic scenario to be monitored for which would be representative of most treatment strategies." (Margaret L. Rodgers, City of Cleveland)

**Response 23:** 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. Some common treatment processes, such as adding pre-oxidants, can cause cells to lyse making it more difficult to remove toxins. 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 24:** "Finished water ELISA-ADDA monitoring should only be required when the raw water analysis indicates raw water toxins are present." (Margaret L. Rodgers, City of Cleveland)

**Response 24:** The raw and finished water monitoring frequency outlined in this rule is necessary due to the transient nature of harmful algal blooms and the need for public water systems to respond rapidly in order to prevent health affects posed by cyanotoxins. Since blooms can be highly variable, especially in the warmer summer months, there would be a strong potential for water systems to continuously go on and off finished water sampling requirements, which would complicate monitoring schedules and make compliance more difficult.

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

**Comment 25:** "We have continuing concerns with the term 'Treatment Technique' as used in the proposed rules. These concerns were discussed in our October 23, 2015 comment letter. This includes the inappropriate use of the term and the application of it towards the treatment of cyanotoxins. There is more than one way to treat for toxins and different strategies might be more appropriate given different source water circumstances for a particular utility." (Margaret L. Rodgers, City of Cleveland)

**Response 25:** "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. 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.

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 26:** "OAC 3745-90-05(A)(2) states a Cyanotoxin Treatment Optimization Protocol must be submitted within 30 days of a raw or finished water microcystin detection. It is assumed this level is 0.3 µg/L based upon the ELISA-ADDA test.

Please clarify this intention since it appears a Treatment Technique violation hinges on this level." (Margaret L. Rodgers, City of Cleveland)

**Response 26:** Requirements to submit a Treatment Optimization Protocol are based on ELISA-ADDA test microcystins results above 0.3 µg/L. "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 27:** "Please explain how Ohio EPA can issue a Treatment Technique violation for a Cyanotoxin Treatment Optimization Protocol. It does not appear any approval or acceptance mechanisms are provided in the rule, and therefore, no official review or response procedure is provided which is needed to make this an enforceable document." (Margaret L. Rodgers, City of Cleveland)

**Response 27:** OAC 3745-81-01 defines a treatment technique as a method for treating water to achieve acceptable levels of the contaminants in lieu of establishing an MCL. For OAC 3745-90-05(A), the treatment technique is the list of actions that the PWS is and/or will take to optimize treatment for microcystins. The rule includes several examples of effective treatments for microcystins, but allows for systems to consider additional options to provide flexibility as new treatments are identified. Ohio EPA will not be formally approving the treatment optimization plans. The enforceable requirement is the submission of the optimization plan and the treatment technique violation would occur if a system does not submit the plan.

**Comment 28:** "Omit this entire section. It is unnecessary because water treatment plants will seek the most up-to-date advice as to their options to reduce algal toxins. These requirements are unreasonably costly and time consuming. If a utility is struggling with cyanotoxins, the pressure of having to submit a plan within 30 days is unreasonable. Most of these plans already exist in EAPs or EOPs which are already in Ohio EPA's possession. If these are not sufficient, then Ohio EPA should work directly with each utility to correct the deficiencies. Further, a cyanotoxin general plan should not create a tier 2 notification if it is not completed within the required timeframe." (John O. Moore, City of Akron)

**Response 28:** See Response #9.

**<u>3745-90-06, Harmful algal blooms – Tier 1 public notification and consumer confidence reports</u>**

**Comment 29:** "Cleveland Water continues to believe the proposed rules 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. The proposed rules continue targeting sensitive populations at the 0.3 µg/L level for total microcystin, which may or may not be made up of the congeners of concern for public health protection. Public messaging without

knowing the crucial piece of information is overly conservative." (Margaret L. Rodgers, City of Cleveland)

**Response 29:** See Response #2.

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.

**Comment 30:** "OAC 3745-90-06(A) establishes a Tier 1 public notification requirement if either of the microcystin action levels are exceeded with a routine and a repeat sample in the finished water. This regulatory structure appears to be based upon the same structure utilized for Total Coliform routine and repeat monitoring, thereby elevating total microcystin to an acute toxin. This is in direct conflict with the 10-day Health Advisory Level established by USEPA guidance and should be changed."

"We request Ohio EPA review the World Health Organization (WHO) standard for the definition of Tolerable Daily Intake pertaining to one particular algal toxin, Microcystin LR. The definition states this toxin is a chronic toxin, not an acute toxin. If Ohio EPA will not recognize the authority of the WHO, the Ohio EPA should strictly adhere to the 10-day Health Advisory guidance. Messaging at any point before the 10-day milestone is telling the public this is an acute toxin scenario. The WHO did not say this, USEPA did not have the epidemiological support to make this statement, and Ohio EPA should not either." (Margaret L. Rodgers, City of Cleveland)

**Response 30:** See Response #2.

The rules include 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. It should be noted that the rules call for multiple samples (resample and repeat samples) prior to a Tier 1 public notice.

U.S. EPA indicated the 10-day health advisory is sub-acute. Several states, such as Pennsylvania, treat even 10-day health advisories as acute levels not to be exceeded (require immediate Tier 1 public notice). Ohio's draft rules permit some time for treatment adjustments and resampling prior to requiring issuance of a public notice.

**3745-89-08, Reporting of analytical techniques**

**Comment 31:** "3745-90-06(A)(1) and 3745-89-08(A) – Regarding submittal of results, Akron disagrees that cyanobacteria screening should be considered a reportable method. If Ohio EPA wants the information to be reportable, then the data should be considered monitoring instead of screening. Again, Akron does not agree that raw water should be monitored and believes that the raw water screening should be for internal utility use only." "3745-89-08(B)(3) – Results of raw water monitoring and screening should not be legally reportable. Instead, they should be used internally only as decision-making tools by the utility. If raw monitoring data must be used to optimize treatment and adjust further monitoring, then it should not result in public notification requirements." (John O. Moore, City of Akron) (John O. Moore, City of Akron)

**Response 31:** The information is considered screening and not monitoring because detections do not trigger public notices, but will trigger follow-up monitoring for other cyanotoxins by Ohio EPA. Ohio EPA believes including raw water screening is more appropriate, given the state of the science and occurrence data, and less burdensome than requiring monitoring and reporting for all the cyanotoxins (see response to comment 6). Raw water screening is necessary to be protective of human health in relation to other cyanotoxins. By the effective date of OAC 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.

**End of Response to Comments**