

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Environmental Protection Agency

Regulation/Package Title: 2015 Public Water System Harmful Algal Bloom Rules

Rule Number(s): 3745-90-01 to 3745-90-07, 3745-89-01 to 3745-89-06, 3745-89-08

Date: 12/1/2015

Rule Type:

New

5-Year Review

Amended

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Ohio EPA is proposing to create new Chapter 3745-90 of the Ohio Administrative Code (OAC), which establishes standards for monitoring, reporting and responding to harmful algal blooms (HABs) in source water of public water systems (PWSs). The rules in this new chapter accomplish the following:

- Establishes definitions specific to Chapter 3745-90.
- Establishes drinking water action levels for microcystins, based on U.S. EPA health advisory levels.

- Establishes cyanobacteria screening and microcystins monitoring requirements for PWSs using surface water and consecutive water systems purchasing water from an out of state surface water source.
- Establishes requirements for laboratory certification, analytical techniques and reporting deadlines.
- Requires submittal of written treatment optimization protocols when microcystins are detected in raw or finished water or a distribution sampling point.
- Requires submittal and approval of a cyanotoxin general plan for PWSs that exceed 1.6 micrograms per liter in a sample collected at the raw water sampling point more than once within a consecutive 12-month period, or when microcystins are detected in a sample collected at a finished water sampling point or a distribution sampling point.
- Establishes requirements for public notification and consumer confidence reporting.
- Sets forth recordkeeping requirements.

In addition, Ohio EPA is proposing to amend several rules in Chapter 3745-89 of the OAC which contains the laboratory certification rules.

- 3745-89-01 incorporates definitions for terms covered in Chapter 3745-89.
- 3745-89-02 explains the qualifications a laboratory must have in order for its analyses to be acceptable for determining compliance with various drinking water rules in the OAC. A provision was added allowing an out of state laboratory to perform analyses for drinking water contaminants for samples collected by a PWS outside the state of Ohio, which provides water to a consecutive water system in the state of Ohio. The out of state laboratory has to meet the analytical and reporting requirements of Chapter 3745-89.
- 3745-89-03 explains the procedure for obtaining laboratory certification, including fee information established in section 3745.11 of the Ohio Revised Code (ORC). The rule also references the latest editions of Ohio EPA's two laboratory manuals for microbiological analyses of public drinking water and chemical analyses of public drinking water.
- 3745-89-04 describes the process and requirements for renewal of a laboratory's certification.
- 3745-89-05 describes the requirements for maintaining laboratory certification.
- 3745-89-06 describes the reasons for which the Director of Ohio EPA may deny, suspend or revoke a laboratory's certification and the process by which issuance, denial, suspension or revocation of certification will occur.
- 3745-89-08 establishes reporting requirements of analytical results for determining compliance with various drinking and ground water rules in the Administrative Code.

The draft amendments to this chapter coincide with the proposal of the new Chapter 3745-90 and include revising the definition of proficiency test, which allows for more flexibility on acceptable providers; referencing the new chapter in order to ensure analytical requirements for laboratory certification meet existing requirements; including requiring laboratory certification and renewal fees for the new chapter; incorporating the new chapter into requirements specifying how and when analytical results are to be reported to Ohio EPA; and removing outdated references.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The new rules will be adopted under the authority of ORC sections 3745.50(C), 6109.03 and 6109.04. Ohio Senate Bill 1, recently passed by the Ohio legislature, enacted ORC section 3745.50(C), which requires the Director of Ohio EPA to develop and implement protocols and actions for cyanotoxin testing in PWSs. ORC section 6109.04 grants the Director authority to adopt rules governing PWSs in order to protect public health.

ORC section 3745.11 paragraph (N)(3) provides the legislation necessary to require laboratory fees.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

OAC Chapter 3745-90 does not implement federal requirements, but is based on the “Drinking Water Health Advisory for the Cyanobacterial Microcystin Toxins,” document published by U.S. EPA in June, 2015. As such, OAC Chapter 3745-90 protects drinking water sources from potential contaminants as outlined in the Safe Drinking Water Act (SDWA).

OAC Chapter 3745-89 does implement federal requirements. These regulations enable Ohio EPA to administer the SDWA, as well as retain primary enforcement authority (C.F.R. 40 Part 142.10) from the Federal Government. These rules establish a State program for the certification of laboratories conducting analytical measurements of drinking water contaminants pursuant to the requirements in the SDWA.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

There is no direct federal counterpart for OAC Chapter 3745-90. However, Ohio EPA is referencing the “Drinking Water Health Advisory for the Cyanobacterial Microcystin

Toxins” and “Recommendations for Public Water Systems to Manage Cyanotoxins in Drinking Water” documents published by U.S. EPA in June 2015. These documents provide recommendations for responding to the health advisory level for microcystins, which the Agency is incorporating into the rules. The microcystins health advisory level will be adopted as an action level, triggering response to microcystins in finished drinking water, including when to notify the public of an exceedance.

While U.S. EPA has indicated several analytical methods for microcystins are acceptable, Ohio has included only one specific method (ELISA-ADDA) in the rules, which could be considered as exceeding the federal recommendations. In making this determination, Ohio EPA carefully reviewed the analytical methodologies currently available, including performing a comparative analysis and an evaluation of potential interferences. The analytical method included in the rule is the least expensive of the three methods deemed acceptable by U.S. EPA and provides the quickest results. Ohio EPA will also be requiring raw water sampling and analysis for cyanotoxin screening via the qPCR analytical method. U.S. EPA recommends raw water screening but does not specify use of the qPCR method, so this could be considered exceeding the scope of the federal recommendations. Ohio EPA selected use of qPCR because the method can be certified, whereas other screening methods cannot be certified. Both the ELISA-ADDA and qPCR methods are Ohio EPA analytical methodologies, as there are not currently federally-approved methods.

OAC Chapter 3745-89 continues to exceed the scope of federal requirements for other regulated contaminants by not accepting all federally approved analytical methods. Specifically, Ohio EPA’s Laboratory Certification Program does not certify ASTM methods. ASTM methods are almost identical to their Standard Method counterparts. The difference is in the quality control (QC) requirements for the ASTM methods, which are less stringent than those in Standard Methods. The more stringent Standard Methods allow for greater confidence in the results and the associated QC requirements.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The purpose for adopting this new Chapter is to ensure the availability of a safe and adequate supply of public drinking water. These rules help to achieve this purpose by ensuring PWSs provide drinking water that is protected from contaminants by prompt detection and effective treatment of the most prevalent cyanotoxins created by harmful algal blooms.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The Agency will base success of all of the rules in this package on PWS compliance rates within our drinking water programs. PWS compliance rates are typically discovered through reported data, during sanitary surveys of said system and review of the treatment optimization plan and cyanotoxin general plan. The Agency will also base the success of these rules on the prevention of microcystins action level exceedances in finished water at public water systems.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

Stakeholders include PWS owners and operators, consultants, environmental organizations, other state agencies, businesses, U.S. EPA and in general, the public at large. The only measure someone has to take to be notified of DDAGW's potential rule activity is to request to be added to our electronic or hard-copy mailing list.

Stakeholders were notified of DDAGW's plans to revise rules on June 1, 2015, with the early stakeholder outreach/comment period ending on June 30, 2015. In addition, DDAGW sought comment from stakeholders during the division's interested party review period held September 22 to October 23, 2015. During the interested party review period, Ohio EPA held an informational webinar and met with representatives from the the American Water Works Association (AWWA) – Ohio Section and Ohio Rural Water Association (ORWA). Ohio EPA also contacted key stakeholders to discuss potential revisions to the rules based on comments received during the interested party review period.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The division received comments during early stakeholder outreach, held from June 1 – June 30, 2015. Representatives of five PWSs provided comments on Ohio EPA's questions, ranging from regulatory focus (which systems to target and for which cyanotoxins to sample) to analytical methods that should be used, and what should be done if finished water concentrations exceed a U.S. EPA Health Advisory Level. The following is a summary of suggestions and comments from the PWSs and how those comments were addressed.

- The current science does not support mandated regulation of HABs by the Agency. U.S. EPA has a rigorous process that is used to develop safe drinking water regulations. Ohio EPA should not proceed with regulation until U.S. EPA has completed the proper research, determination of health effects and corresponding levels of concern (acute and chronic), development of proper analytical methods for analyzing and reporting, evaluation of cost/benefit considerations, and appropriate public commenting necessary to establish a maximum contaminant level (MCL) or treatment technique.

Ohio EPA response: U.S. EPA conducted an extensive toxicological review to develop the health advisory concentrations for microcystins. Other states have required public notification if U.S. EPA health advisories are exceeded in drinking water. Given the occurrence of microcystins in Ohio water sources, Ohio EPA believes the rule is necessary to protect human health. Ohio Senate Bill 1 enacted ORC section 3745.50(C), which places an expectation on Ohio to address this concern. Ohio EPA has utilized the ELISA method for the detection of microcystins for over five years and has confidence in the results of the analysis. Ohio EPA's method comparison study and collaboration with other researchers has shown that the method is reliable for the detection of total microcystins (no false positives or negatives). Ohio EPA continues to evaluate new analytical methods as they become available. There is a provision in the rule to permit use of an alternate analytical method if deemed acceptable to the director.

- Costs to PWSs need to be evaluated. The toxin analysis by employees is time consuming and it requires specialized staff. The tests themselves are also expensive and it may cost to install additional treatment if needed. There is also concern with sample results being reliable.

Ohio EPA response: The microcystins analysis method included in the draft rule is the least expensive and least time consuming of the analytical methods recommended by U. S. EPA in their implementation guidance. If PWSs do not want to analyze samples in their lab, due to lack of time or specialized staff, they can send samples to an independent lab for analysis. Ohio EPA's method comparison study and collaboration with other researchers has shown that the method is reliable for the detection of total microcystins (no false positives or negatives).

- There are concerns about the Agency's approach on public communication, which is more aggressive than what U.S. EPA put forth in their final implementation guidance. Public notification of a water use advisory from a large utility costs millions of dollars. Also and more importantly, there is a loss in public confidence of water

treatment when notification is issued prematurely, if the Agency decides to issue an advisory based on one sample above the U.S. EPA Health Advisory Level.

Ohio EPA response: Ohio EPA agrees that an advisory should not be issued after one sample exceedance. Ohio does take the 10-day exposure duration into consideration. The rule requires at least one additional sample above the action level prior to issuance of an advisory. The rule also indicates that the scope of an advisory can be limited based on distribution system results and in some cases an advisory may not be issued until a third set of samples indicates an exceedance of the action level. Ohio EPA, however, also believes there is a greater risk of loss of public confidence if results are not shared with the public in a timely manner.

Several recommendations were made on the direction of developing rules and are described in the following paragraphs:

- Ohio EPA should focus on water systems that have known significant problems with HABs rather than regulate all surface water PWSs.

Ohio EPA response: Microcystins occurrence data has not been collected for all surface water systems in Ohio, so a decreased monitoring schedule is not appropriate based on the incomplete historic occurrence data alone. Once data is available, there are provisions in the rule that could permit a decreased monitoring schedule.

- Suggestions for what to monitor and how often varied. Microcystins and cylindrospermopsin were recommended, but some commenters suggested forgoing cylindrospermopsin because it is rarely found in surface water systems in Ohio. It was recommended that anatoxin-a not be included until more information is available. One commenter suggested focusing on those microcystin congeners shown to pose a risk to public health. Suggestions on monitoring included focusing on raw water cell and raw water toxin monitoring; monitoring finished water monthly and increasing frequency if other water quality parameters indicated existence of cyanobacteria or cyanotoxins; and sampling raw water only during June 1 to October 1, with finished water sampling beginning when there are detections in the raw water and continuing until there are no detections in the raw and finished water. The latter proposal included sampling once every 10 days, but samples could be collected more frequently if utilities desire. It was also suggested that finished water samples are collected near the first customer, since chlorination degrades microcystins over time.

Ohio EPA response: The draft rule only applies to microcystins and screening data. We agreed with the commenters that cylindrospermopsin and anatoxin-a were not detected on a frequent enough basis to require routine monitoring as part of this rule. Since health advisories have not yet been established for saxitoxins, we agreed that the rules should not include saxitoxins at this time. To be protective of human health,

the screening data will provide information on potential for presence of other cyanotoxins in the source water. Based on those indicators, Ohio EPA will continue to sample for the other cyanotoxins in raw and finished water. The rule also allows for decreased microcystins monitoring in the future if screening data support that reduction. The screening data will also be used to inform whether or not future rules should include monitoring and reporting requirements for the other cyanotoxins. Ohio EPA has included year-round sampling requirements rather than limit it to only June 1 to October 1, because microcystins have been detected at high concentrations outside of that date range.

- Recommendations for reporting sample results included monthly for all results, monthly for results below health advisory levels, within 24 hours of receipt for results above a health advisory level, and within 48-72 hours of the initial threshold trigger for both the initial and follow-up sample results.

Ohio EPA response: The draft rule establishes reporting requirements consistent with other parameters (within ten days after the end of month, except finished water detections, results in raw water samples greater than 5 micrograms per liter ($\mu\text{g/L}$), and results of cyanobacteria screening that indicate the potential for production of other cyanotoxins, which are required to be reported by the end of the next business day).

- Recommendations were made to create an ELISA certification program and to only use the ELISA test method as a screening tool and to allow the use of other analytical methods, including those recommended by U.S. EPA. It was also suggested that a validated LC/MS/MS 544 method be used for confirmation of finished water samples that exceed the health advisory level because it would improve the reliability of results. In addition, it was recommended Ohio EPA not require LC/MS/MS MMPB since it seems only one lab in the world is using the method. It was suggested that LC/MS/MS could be used to determine total microcystins by summing the results for the -LR, -RR, -YR, -LA, -LF, -LY congeners. Additionally, while a comment was received favoring the 544 LC/MS/MS method over the MMPB LC/MS/MS method, another comment recommended that 544 not be required due to the time required for analysis. It was also suggested the Agency commit to analyzing samples for utilities that do not have the expertise or resources to do so. Lastly, a recommendation was made to ensure laboratories are available on a twenty-four hour, seven days per week basis for LC/MS/MS 544 for the assurance of obtaining reliable data prior to a health advisory being issued.

Ohio EPA response: Ohio EPA has included an ELISA certification program as part of the rule package. Since the U.S. EPA health advisory was developed for total

microcystins, U.S. EPA's LC-MS/MS Method 544 is not an appropriate method since it only measures six of the over 100 microcystin variants. Ohio EPA conducted a variant analysis of a range of Ohio source waters and 90% of the samples contained microcystin variants that are not detected by Method 544. Based on the method comparison study results, Method 544 would consistently under-report total microcystins and not be protective of human health. Ohio EPA continues to evaluate new analytical methods as they become available. Ohio EPA agrees with commenters that the LC-MS/MS MMPB method is not currently viable due to lack of validation and limited lab capacity; however, this method may be acceptable if the method is interlab validated and lab capacity is improved. There is a provision in the rule to permit use of an alternate analytical method if deemed acceptable to the director.

- It was also suggested to allow PWSs to start algal toxin treatment after the single sample that exceeds the health advisory level and to delay issuing an advisory until the sample is confirmed. Additionally, recommendations were made that if finished water concentrations exceed the health advisory level in a single sample, the system immediately resample finished water (along with an initial retest of the sample testing positive) immediately, within 36 hours, and daily (if not already doing so), and issue public notice if finished water concentrations have exceeded the health advisory level for at least five consecutive days. If the finished water sample is confirmed to exceed the health advisory level for ten consecutive days, a do not use advisory should be issued to those affected. When finished water concentrations are confirmed to exceed a U.S. EPA Health Advisory Level, various approaches were recommended for determining the timing of a public notice and a drinking water advisory. These included averaging, as recommended by the Ohio AWWA Section, for microcystins and waiting until health advisory levels are exceeded for five (public notice) or ten (do not use advisory) consecutive days.

Ohio EPA response: Ohio EPA agrees that an advisory should not be issued after one sample exceedance. The rule requires at least one additional sample above the action level prior to issuance of an advisory. The rule also indicates that the scope of an advisory can be limited based on distribution system results and in some cases an advisory may not be issued until a third set of samples indicates an exceedance of the action level (dependant, in part, on the amount of time that has passed since the last sample where microcystins were not detected). Ohio EPA, however, disagrees with waiting until the health advisory level has been exceeded for five consecutive days prior to issuance of an advisory. That approach is contrary to recommendations provided by U.S. EPA and is not protective of human health.

The division also received several sets of comments during the interested party review period, held from September 22 – October 23, 2015. A summary of all comments and Ohio EPA’s responses to them, along with a summary of changes made to the rules since the interested party comment period, are available online at <http://epa.ohio.gov/ddagw/rules.aspx> or by request from Ohio EPA’s, Division of Drinking and Ground Waters by calling (614) 644-2752.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

New OAC Chapter 3745-90 is based on the best scientific data available as guidance for public and environmental health agencies and organizations. The draft rule adopts action levels from U.S. EPA health advisory levels for microcystins, which were based on a comprehensive analysis of available toxicological data and were subjected to peer review by leading national and international scientists. A list of references used in the development of these rules is located in the references section of Ohio EPA’s “Public Water System Harmful Algal Bloom Response Strategy” (July 2015). Note: Ohio EPA intends to update this document prior to the 2016 HAB season to describe how the new regulatory approach to microcystins and cyanobacteria screening will be incorporated into the broader, statewide HAB program.

Ohio EPA also carefully reviewed the analytical methodologies currently available, including performing a comparative analysis using samples collected from a range of representative Ohio source waters and an evaluation of potential interferences.

Ohio EPA obtained statutory authority in Chapters 6109. of the Revised Code for the laboratory certification rules and promulgated them under Administrative Code 3745-89. References used include the latest revisions to 40 C.F.R. Parts 141 and 142. The federal counterparts which include the SDWA Amendments of 1996 are the foundation for these rules.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives?

The Agency considered many different options in developing OAC Chapter 3745-90. These included when and where to sample, how frequently, for which parameters, using which methodologies, etc. Offering a reduced monitoring option was considered for systems with little or no evidence of HABs and/or avoidance strategies or treatment capability that could address any level of contamination by HABs. However, this was ultimately rejected due to the unpredictable nature of HABs, which can appear suddenly in a water body that has never

experienced them previously, and the difficulty of adequately addressing in a rule all the variables involved. This may be an option considered in the future when routine baseline data has been collected.

In order to retain primary enforcement authority, Ohio EPA is required to establish a laboratory certification program and adopt rules. Therefore, Ohio EPA could not consider alternatives to these rules. In the future, Ohio EPA may look at accreditation for out of state laboratories.

11. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Yes, most of the rules in OAC Chapter 3745-89 are performance-based and contribute to the accuracy of drinking water analysis used to determine compliance with primary and secondary drinking water standards. Additionally, some of the new rules in OAC Chapter 3745-90, in particular the cyanotoxin general plan, are performance-based.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

There are no existing rules regulating PWSs with regards to harmful algal bloom monitoring and reporting. In respect to OAC Chapter 3745-89, Ohio EPA reviewed internal regulations and determined there are no duplications.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Ohio EPA held several internal trainings and will continue to conduct trainings and discussion forums on the new rules as needed.

Ohio EPA implementation of this rule package includes the following:

- Seeking input from staff on implementation problems and developing solutions.
- Involving staff in developing rule amendments.
- Developing internal procedures and guidance documents for staff to use in implementing rules.
- Regularly notifying staff of rule changes.
- Giving presentations on rule updates.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

3745-90-01 and 3745-90-02: There is no cost of compliance associated with these rules.

3745-90-03: The impact of this rule would be to the PWS, whether they conduct the monitoring themselves or contract with a commercial laboratory.

3745-90-04: The impact of this rule is to commercial laboratories and the PWSs that are conducting analysis, as there is a charge for certification. To allow for adjustment to this new program, this charge will be delayed until one year after the effective date of the rule.

3745-90-05 and 3745-90-07: The impact of these rules is primarily to the PWSs.

3745-90-06: This rule has an impact on the PWS, their consumers, the local leadership of the community, and the many agencies involved in issuing a public drinking water advisory.

3745-89-01 to 3745-89-06, 3745-89-08: All drinking water laboratories in the State that are certified by Ohio EPA, including private laboratories and PWSs with their own laboratory.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

3745-90-03: PWSs would bear the cost of taking samples, which includes labor and materials. PWSs that conduct their own analysis would additionally bear the cost of maintaining the analytical equipment and increased time spent by their staff. PWSs that submit their samples to a commercial laboratory would bear the costs of sample containers, shipping and the costs charged by the laboratory. Until such time as there is sufficient certified laboratory capacity to conduct the cyanotoxin screening analysis, Ohio EPA's Division of Environmental Services (DES) will fulfill this need. To provide some assistance and relief for these costs, Ohio EPA has previously made \$1 million dollars in grants available to public water systems to establish their own analytical capabilities.

3745-90-04: There is a standard fee for laboratory certification by Ohio EPA's Division of Environmental Services (DES).

3745-90-05: This rule requires PWSs to develop written treatment optimization protocols for when microcystins are detected in raw water or finished water sampling points. The treatment optimization protocols should include considering effective strategies for cyanotoxin treatment, such as optimizing existing treatment and removal of intact cyanobacterial cells. In addition, PWSs will be required to submit a cyanotoxin general plan, in instances where microcystins concentrations exceed 1.6 µg/L in two or more samples within a consecutive 12-month period collected at the raw water sampling point, or when microcystins are detected in a sample collected at a finished water sampling point or a distribution sampling point. The direct cost is primarily employee time spent developing the treatment optimization protocols and a professional engineer drafting a cyanotoxin general plan, in addition to a plan approval fee. Treatment costs would depend on the actual approved optimization protocols and the cyanotoxin general plan. To provide some assistance and relief for these costs, Ohio EPA continues to provide funding assistance through zero- to low-interest loans for planning and infrastructure improvements.

3745-90-06: This rule requires PWSs to issue a Tier 1 public notification using specifications outlined in this rule and existing rule 3745-81-32 of the OAC. It also requires community PWSs that exceed a microcystin action level in a sample collected from a finished water sampling point or a distribution sampling point to provide specific detail in the annual consumer confidence report.

3745-90-07: The cost to comply with this rule is primarily to PWSs that maintain paper records and need to acquire storage.

Adverse impacts to rules in Chapter 3745-89 include the following:

- PWS laboratories and private laboratories must be certified by Ohio EPA to analyze drinking water for the purpose of determining PWS compliance with safe drinking water standards in OAC Chapters 3745-9, 3745-81, 3745-82 and 3745-91.
- Laboratories applying to be certified are required to submit a quality assurance plan, documentation of each individual performing the analysis, a certification fee and undergo an onsite survey. All laboratories that become certified in the State of Ohio are required to renew their certification once

every three years, as well as if or when they apply to be approved for analysis of a different contaminant.

- Certified laboratories are required to maintain documentation of their analysis, the individuals conducting it and to report analysis to Ohio EPA as part of complying with their certification.
- Certified laboratories applying for interim authorization for plant control tests, new contaminants and new methods will be required to submit an application and undergo an Ohio EPA onsite survey for approval from the Agency.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

3745-90-03: The cost to comply with this rule would include cyanotoxin screening and monitoring for microcystins. To provide some assistance and relief for these costs, Ohio EPA has previously made \$1 million dollars in grants available to public water systems to establish their own analytical capabilities. Each surface water system could receive up to \$30,000 to offset set up costs. The frequency of sampling will depend on the time of year, results from the routine samples, whether finished water detections occur, and analytical costs. In general, the costs would most often account for sampling and shipping materials. Labor costs vary depending on the size and type of the PWS, as well as the individual salaries and whether or not the PWS has its own certified laboratory to conduct microcystins analysis.

Cyanobacteria Screening

Surface water systems are to collect a minimum of one sample from each raw water sampling point at least once every two weeks. The average amount of time to collect this sample and provide it to a certified laboratory for analysis is about 30 minutes. The average cost of this screening using the qPCR method for twenty-six weeks ranges from \$70 to \$183 per sample or \$1,820 to \$4,758 per year.

Ohio EPA will cover analysis expenses for at least the first year from when this rule becomes effective, but PWSs will have to pay for sample shipping at an estimated cost of \$23 to \$60 per shipment or \$598 to \$1,560 per year.

Microcystins Monitoring

Ohio EPA received various estimates from small to medium-size PWSs. These estimates were based on the original proposal to require PWSs to conduct

microcystins monitoring weekly for a total of fifty-two weeks per year. These cost estimates ranged from \$12,000 to \$25,000. The following paragraphs incorporate revised cost estimates based on the proposed revisions to the rule.

Monitoring and analysis during the time period May 1 – Oct. 31: Surface water systems are to monitor with a minimum of one sample from each raw water sampling point and one sample from each finished water sampling point at least weekly. In some cases, this analysis will be conducted by the PWS. The average amount of time to conduct this analysis is five hours. The average cost of this monitoring using the ELISA-ADDA method for twenty-six weeks (six months) ranges from \$70 to \$150 per sample or \$3,640 to \$7,800. PWSs that have to ship samples to an outside laboratory would also have to pay for shipping and sample containers at an estimated cost of \$23 to \$60 per shipment or \$598 to \$1,560 for the six month period. PWSs may incur an additional one-time cost to purchase a cooler for shipping samples.

Monitoring and analysis during the time period Nov. 1 – April 30: Surface water systems may reduce monitoring to a minimum of one sample from each raw water sampling point at least once every two weeks if at least two consecutive weekly samples from both the raw water and finished water sampling points are non-detect for microcystins. Assuming the system will be able to remain on a reduced monitoring schedule, the average cost of monitoring for microcystins in only raw water using the ELISA-ADDA method for thirteen weeks (six months) ranges from \$70 to 150 per sample or \$910 to \$1,950. PWSs that have to ship samples to an outside laboratory would also have to pay for shipping at an estimated cost of \$23 to \$60 per shipment or \$299 to \$780 for the six month period.

Total annual costs for microcystins monitoring and analysis for a system which can reduce sampling between November and April will range from \$4,550 to \$9,750. If the water system continues to detect microcystins in source water during this time period and is not eligible for reduced monitoring, the total annual costs will range from \$7,280 to \$15,600. If shipping is necessary, the cost will range from \$897 to \$3,210 per year depending on whether the PWS is eligible for reduced monitoring.

The costs figure for microcystins monitoring do not account for surface water systems with more than one raw water sampling point. It also does not account for increased monitoring that may be required if microcystins exceed 5.0 µg/L at the raw water sampling point or microcystins are detected in finished water.

To provide some assistance and relief for these costs, Ohio EPA has previously made \$1 million dollars in grants available to public water systems to establish their own analytical capabilities.

3745-90-04: DES's standard laboratory certification fee is \$1,550 and is renewable every three years. The costs to comply with this rule are established in OAC Chapter 3745-89. To allow for adjustment to this new program, this charge will be delayed until one year from the effective date of the rule.

3745-90-05: This rule requires written treatment optimization protocols and/or a cyanotoxin general plan, so the direct cost is primarily employee time spent or that of a professional engineer developing either or both of the two. There is a general plan approval fee, which is \$150. The cost of implementing the plan will vary substantially and be dependent upon the selected approach. Examples of approaches that might be in the general plan include installing ozone, increasing or adding a powdered activated carbon (PAC) feed, and a reservoir management program. If the PWS already has advanced treatment in place that is capable of cyanotoxin destruction or removal, the general plan can serve to document the existing treatment is effective and additional treatment is not necessary. The costs of a general plan can vary from minimal (the time it takes for an operator to document existing treatment processes) to \$20,000-\$100,000 (the cost associated with planning necessary for a substantial plant upgrade). To provide some assistance and relief for these costs, Ohio EPA continues to provide funding assistance through zero- to low-interest loans for planning and infrastructure improvements.

3745-90-06: This rule does not directly impose costs on PWSs, but does establish the framework for when to issue a Tier 1 public notice. It also requires some community PWSs to include information about exceedances of the action level in their annual consumer confidence report.

The overall cost of compliance to systems is already established in OAC rule 3745-81-32. The estimates include personnel costs, new equipment or other capital costs, operating costs and any indirect central service costs associated with public notice preparation and distribution. In 2009, this estimate, per system with a violation triggering public notification, ranged from \$1,535.43 for PWSs serving 3,301 to 10,000 up to \$50,106.10 for PWSs serving over 100,000.

The overall cost of compliance to community water systems that are required to issue a consumer confidence report is already established in OAC Chapter 3745-96. The

estimate includes the cost of development and delivery of the report. In 2010, the cost to each system to comply with OAC Chapter 3745-96 was estimated at \$400.92 per year.

In addition to the cost of the Tier 1 public notice as described, PWSs provided Ohio EPA with information addressing the costs to the community of issuing a public notice and specifically, a “Do Not Drink/Do Not Boil” advisory. The estimates provided by the article are a range of \$103 to \$220 per person per day, which does not include the costs for delivery and distribution of alternate sources of water [Roberson, J. Alan; Carpenter, Adam T. (2015). Cyanotoxins: Practical Solutions Needed. *Journal AWWA*, 107:10 (Oct. 2015), pp. 12-15.] Ohio EPA also recognizes an unquantifiable cost to communities in loss of public confidence as a result of issuing a Tier 1 public notice.

3745-90-07: The costs depend on the volume of records to be maintained and the method chosen for maintaining them. PWSs may choose to maintain electronic or physical copies of records. For PWSs maintaining paper records, the volume of records will vary depending on the size of the system, from one filing cabinet’s worth of records to an entire filing room. The cost to comply with this rule could therefore range from \$360 to \$800 (a one-time cost for a standard 5-drawer filing cabinet, depending on the type and a couple of boxes of file folders and hanging filing folders at Staples.com), to an annual cost of \$1,500 (approximate cost for maintaining an account with National Resource Centers, who have off-site locations in five cities in Ohio).

3745-89-02 to 3745-89-04: Most of the costs to comply with these rules are existing costs previously identified, with the exception of a new fee as noted below.

Certification Fees

OAC rules 3745-89-03 and 3745-89-04 require that laboratories in Ohio be certified every three years to perform analysis of drinking water. Approximately 382 certified laboratories exist in Ohio at this time, many of which maintain multiple certifications. County, township and municipal labs account for approximately 95% (362 labs) of the certified laboratories in Ohio. The remaining labs are privately owned. Ohio EPA records indicate that the total annual cost for all labs in Ohio to maintain their certification is approximately \$517,650.00 (May 2013). The standard fee for a three year renewal is \$1,550.00. A new \$1,550 fee for certification of total microcystins and cyanobacteria screening has been added and must be renewed every three years.

To allow for adjustment to this new program, this charge will be delayed until one year after the effective date of these rules.

The new provisions in this rule will increase the cost of compliance for the laboratories wanting to become certified to perform microcystins and cyanobacteria analyses. Currently, the Division of Environmental Services, Laboratory Certification Section has given temporary acceptance to some certified laboratories that are using the appropriate techniques for these analyses. If every laboratory that currently has acceptance would apply for certification to perform these analyses, then every three years the Laboratory Certification Section would see increased revenue of about \$43,000.

Proficiency Testing

As part of the laboratory certification program, labs must perform analysis of proficiency test samples annually. Based on price quotes from various vendors, the total annual costs for all labs in Ohio are estimated at \$144,155.00.* This estimate includes the cost of the product. All other costs (e.g., indirect and personnel) are negligible.

*The estimates presented were updated using the U.S. Bureau of Labor Statistics inflation calculator from 2008 to 2013.

Quality Assurance Plan

As part of the certification process, laboratories must submit a quality assurance plan for approval by the Director. Depending upon the number and type of certifications for which the lab applies, the cost will vary. Some labs are only certified to perform very basic testing, while others may be certified to perform more extensive testing. High and low estimates for developing the plans are outlined below. These costs were obtained from various labs in Ohio and from Agency personnel. Costs to develop these plans include personnel costs to write the plans and indirect (e.g., copying, mailing, updating, etc.) costs. Capital and operational costs are not applicable. Estimates for developing the plans ranged from ten to ninety hours. Estimates on rates of lab personnel who write the plan vary from \$11.00 to \$54.00 per hour.*

*The estimates presented were updated using the U.S. Bureau of Labor Statistics inflation calculator from 2008 to 2013.

Quality Assurance Plan Expenses

Cost Category	Low Estimate	High Estimate
Personnel Costs	10 hours at \$11/hour = \$110	90 hours at \$54/hour = \$4,860
Indirect Costs	15% of \$110 = \$17	15% of \$4,860 = \$729
Totals	\$127	\$5,589

Totals

Total statewide costs for this rule (on an annual basis) are approximately:

Certification Fees: \$517,650.00

Proficiency Tests: \$144,155.00

\$661,805.00 (Average of \$1,732.00 per lab)

In addition, each lab will spend approximately \$127 to \$5,589 as a one-time cost to develop a quality assurance plan.

Lastly, if every laboratory with current acceptance to perform the microcystins and cyanobacteria analyses applied to become certified, the total for certification fees would increase by \$43,000 every three years.

3745-89-05:

This rule requires laboratories to maintain records of their compliance with the certification requirements in Chapter 3745-89. The cost associated with record maintenance includes the cost of storage, and will depend on the volume of records to be maintained as well as how they are maintained. Most laboratories use paper records, while some commercial laboratories have adopted electronic record keeping systems.

For a laboratory using paper records, maintenance could require one to several filing cabinets. The cost could range \$360 to \$800 (a one-time cost for a standard 5-drawer filing cabinet, depending on the type and a couple of boxes of file folders and hanging filing folders at Staples.com), to an annual cost of \$1,500 (approximate cost for maintaining an account with National Resource Centers, who have off-site locations in five cities in Ohio).

The cost for an electronic Laboratory Information System (LIMS) database, for a laboratory processing high volume of samples, is estimated to be between \$40,000 and \$60,000 for hardware and software, and approximately \$271 for an annual software license fee for each person using it.

Please note that commercial laboratories will have LIMS to process all samples regardless of whether or not they are certified for drinking water sampling. This cost is not a direct result of the drinking water laboratory certification program.

3745-89-08:

Certified laboratories are directly affected by this rule and endure the costs to comply with it. Based on a survey of four commercial laboratories, the cost to comply with this rule is approximately \$11 a month, or \$132 annually.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Agency considers the overall cost for complying with these regulations to be necessary for the purpose of ensuring PWSs provide drinking water that is protected from contaminants by prompt detection and treatment of the most prevalent cyanotoxins created by harmful algal blooms.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

OAC rule 3745-90-06 allows some flexibility regarding when a public water supplier must issue an advisory, based on the results of resamples or distribution system samples.

OAC rule 3745-90-04, which addresses laboratory issues, refers to Chapter 3745-89 of the Administrative Code, which allows for alternate laboratory analytical procedures, as approved by the Director.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Ohio EPA does not assign fines and penalties for first-time offenders, and prefers to obtain compliance through outreach first and if needed, written notice of violations prior to any type of formal enforcement.

18. What resources are available to assist small businesses with compliance of the regulation?

Small business PWSs can turn to their Ohio EPA District Office Inspector and HAB Coordinator for technical assistance. Ohio EPA also provides technical training for PWSs at low to no-cost.

In addition, the Rural Community Assistance Program (RCAP) can provide technical assistance. Ohio EPA contracts with RCAP to provide assistance for PWSs with a population of 10,000 or less. RCAP can help small business PWSs with a number of tasks, such as:

- Preparing loan applications, including determining the ability to repay;
- Determining the most cost effective action for providing a safe drinking water supply;
- Developing and/or completing their capability assurance plan.

RCAP sponsors training seminars, such as utility board training, financial management, asset management, and budget and rate setting training.

Ohio EPA's Office of Compliance Assistance and Pollution Prevention (OCAPP) is a non-regulatory program that provides information and resources to help small businesses comply with environmental regulations. OCAPP also helps customers identify and implement pollution prevention measures that can save money, increase business performance and benefit the environment. Services of the office include a toll-free hotline, on-site compliance and pollution prevention assessments, workshops/training, plain-English publications library and assistance in completing permit application forms. Additional information is available at <http://www.epa.ohio.gov/ocapp>.

In addition to these informational resources, financial assistance may be available through Ohio EPA's Drinking Water Assistance Fund (DWAF). In April 2015, Ohio EPA made \$1 million in grants available to surface water PWSs to enhance their monitoring capacity for cyanotoxins and harmful algal blooms. A PWS can apply for up to \$30,000 to purchase equipment for monitoring and analysis and to fund training. Fifty million dollars in zero-percent interest rate loans were also made available to surface water PWSs for enhanced water treatment infrastructure.

The majority of certified laboratories in Ohio are owned by PWSs, some being classified as small. Overall, Ohio EPA provides administrative assistance and technical training for all certified laboratories at no cost. Onsite training from DES is given as needed (e.g., a lab is newly approved for a microbiological or chemical analyte).