



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Environmental Protection Agency

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Regulation/Package Title: Harmful Algal Blooms 2020, Amendments

Rule Number(s): 3745-90-01, 3745-90-02, 3745-90-03, 3745-90-04, 3745-90-05, 3745-90-06, 3745-90-07

Date of Submission for CSI Review:

Public Comment Period End Date:

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR?___)

Amended/ X 7 rules (FYR? Yes, 7)

Rescinded/___ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

- 1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. Requires specific expenditures or the report of information as a condition of compliance.**
- d. Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

- 2. Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

Rules in 3745-90-01 through 3745-90-07 of the Ohio Administrative Code (OAC) describe harmful algal bloom monitoring, reporting, analysis and public notification for public water systems. DDAGW has reviewed these rules to satisfy the five-year rule review requirements of section 106.03 of the Ohio Revised Code, and are proposing to file the rules with the following amendments:

- Defining the parameters of harmful algal bloom (HAB) season and off-season that adjust seasonal period (HAB season June through November, off-season December through May).
- Modify definition of cyanobacteria screening and adding the definitions for consecutive samples, resample, and repeat sample.
- Ending the same day requirement for total microcystin and cyanobacteria screening samples in 3745-90-03(A)(1).
- Remove monitoring requirement (sampling three times per week) when raw water microcystins exceed five micrograms per liter.
- Reduce monitoring requirement from daily to three times per week when microcystins are detected in finished water.
- Change sample point for microcystins monitoring from raw to finished water sampling point during off-season period 3745-09-03(A)(2)(b).

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- Update version to method reference for cyanobacteria screening and total microcystins analysis 3745-90-04(C). Note that revised total microcystins method 701.0 version 2.4 (April 2021) reduces reporting limit to 0.22 micrograms per liter.
- Removal of the reporting violation issued in 3745-90-04(E) to public water systems and removal of the requirement to issue a tier 3 notification if results are not reported in accordance with 3745-89-08.
- Adding written treatment optimization protocol requirements (requiring an annual review and requiring protocol submission to the director for review within 30 days of substantial change) for all Surface Water Public Water Systems (PWS).
- Adding requirements for PWS response to Ohio EPA comments regarding cyanotoxin general plan within 30 days of the comment date or other schedule provided by the director.
- Clarification of public notification limited distribution requirements.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The rules have been adopted under the authority of ORC sections 3745.50(C), 6109.03 and 6109.04. ORC section 3745.50(C) 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.

4. 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 (SWDA).

5. 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. Ohio EPA has referenced 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

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for responding to the health advisory level for microcystins, which the Agency has incorporated into the rules. The microcystins health advisory level has been adopted as an action level, triggering response to microcystins in finished drinking water, including when to notify the public of an exceedance.

6. 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 of chapter 3745-90 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.

7. 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.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No

Development of the Regulation

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

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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 8, 2020, with the early stakeholder outreach/comment period ending on July 6, 2020. In addition, DDAGW will seek comments from stakeholders during the division's interested party review period. The interested party review period occurs before the rules are filed with JCARR and is used to address any concerns or questions from staff and our stakeholders.

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

Several comments were received during the Early Stakeholder Outreach phase of rule drafting. Commenters included Ohio Environmental Council, Hull and Associates, LLC, Cleveland Water, Greater Cincinnati Water Works and the Village of Paulding Water. All comments were taken into consideration when drafting the rules. Many comments were focused on disagreements with the annual submission of treatment optimization protocols (TOPs). Based on these comments, DDAGW revised the rule to require an annual review of the TOP and that is available to Ohio EPA upon request. Ohio EPA only requires submission of a revised TOP when substantial change to the protocol, treatment, or source water. Some comments suggested decreased monitoring during off-season, and the revised rule requires monitoring at only the finished water sampling point during off-season. One comment suggested increasing the action levels for total microcystins monitoring when utilizing ELISA methods due to the sensitivity of the analysis. Ohio EPA is revising the microcystins method to lower the reporting limit of this analysis. Additional comments include approving alternative methods for microcystins, specifically congener-specific methods, and alternative method for cyanobacteria screening. The definition of cyanobacteria screening was modified to include semiquantitative methods of cyanotoxin analyses.

11. 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?

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OAC Chapter 3745-90 has been based on the best scientific data available as guidance for public and environmental health agencies and organizations. The rules adopt 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" (May 2019). This document has been updated annually since 2016 (effective year for OAC 3745-90) based on available data from PWS compliance and source water sampling, which were also used to support monitoring reductions in the revised rule.

12. 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?

Alternate compliance monitoring considerations were discussed in early stakeholder outreach - DDAGW was particularly interested in stakeholder input on modifying compliance monitoring such that only entry point monitoring would be required. Responses both supported and were against this idea.

13. 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, many rules in OAC Chapter 3745-90, in particular the cyanotoxin general plan, are performance-based.

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

Ohio EPA reviewed internal regulations and determined there are no duplications.

15. 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 implementation of this rule package includes the following:

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- 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

16. 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.

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.

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

3745-90-03: PWSs would bear the cost of collecting samples, including labor and material cost. PWSs conducting their own analysis would additionally bear the cost of maintaining the analytical equipment and any increased time spent by their staff to do so. PWSs that submit their samples to a commercial laboratory would bear the costs of sampling containers, shipping and the costs charged by the laboratory.

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3745-90-04: There are costs associated with laboratory certification fees. Removal of the reporting violation issued in 3745-90-04(E) to public water systems and the requirement to issue a Tier 3 notification if results are not reported in accordance with 3745-89-08 will also result in decreased cost.

3745-90-05: This rule requires all PWSs receiving water from surface water sources to develop written treatment optimization protocols. The treatment optimization protocols should include considering effective strategies for cyanotoxin treatment, such as optimizing existing treatment and removal of intact cyanobacterial cells, and must be updated at a minimum annually. 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.

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 PWSs data storage requirements.

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 will include cyanotoxin screening and monitoring for microcystins. The compliance cost of this rule will be dependent on the following variables: the time of year (and therefore frequency of sampling), results from the routine samples, whether finished water detections occur, the need for expedited analysis, and analytical costs. In general, the costs would most often account for sampling

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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.

To extrapolate average lab costs, 9 Ohio commercial labs were contacted regarding cost for microcystin analysis and cyanobacteria screening [see Table 1]. A HAB survey was also conducted addressing the following question: “*Please estimate annual water system expenses for compliance monitoring for microcystins and cyanobacteria screening samples (OAC Rule 3745-90, include staff and supply expenses if analysis is completed by the water system)?*” 35 systems responded to this survey question. Responses ranged from \$1,000 to \$100,000 (average: \$17,313; median: \$8,400; mode: \$3,000). The high average costs includes a few systems with multiple facilities (i.e., Cleveland and Columbus). The large range in cost estimations was due to varying elements included in cost estimation (ie not all systems included staff and supply expenses such as employee salary and benefits within their calculations)

Surface Water Systems

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 during HAB season. The average amount of time to collect this sample and provide it to a certified laboratory for analysis is about 30 minutes.

The cost of this screening using the qPCR method ranges from \$50 to \$210 (AVG. \$143.75) [Table 1]. PWSs will have to pay for sample shipping as needed at an estimated cost of \$25.32 to \$66.05¹ per shipment. Sampling once every two weeks throughout the duration of HAB season (6 months, equating to 13 weeks of sampling) will result in a potential range of \$329.16 to \$858.65 for shipment costs.

Microcystins

HAB season monitoring and analysis – routine monitoring: Surface water systems are required to monitor at a minimum of once every two weeks at the raw water sampling location. 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 per HAB season (6 months, equating to 13 weeks of sampling) with routine samples ranges from \$50 to \$100 per sample (AVG. \$82) or \$650 to \$1,300 per HAB season (AVG. \$1,066) [Table 1]. 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 \$25.32 to \$66.05¹ per shipment or \$329.16 to

\$858.65 for the six-month period (13 total weeks of shipment). PWSs may incur an additional one-time cost to purchase a cooler for shipping samples.

If Microcystins are detected during the above HAB season routine monitoring: Weekly monitoring at the raw water sampling point and the finished water sampling point shall be conducted, beginning no later than twenty-four hours following notification of this detection. Initial sampling will likely be at an expedited 24-hr analysis cost if analysis is to be conducted by an outside laboratory, ranging from \$50 to \$270 (AVG. \$170) per sample [Table 1]. Following this initial expedited sample cost, the average cost of this monitoring with routine samples will range from \$50 to \$100 per sample (AVG. \$82). The duration of this sampling will vary – sampling may return to every other week raw sampling following two weeks of non-detects from both raw and finished samples. Any PWS experiencing consistent raw water detections for the duration of a HAB season may cost between \$2,600 to \$5,200 (AVG \$4,264) per HAB season for sample processing (for 26 weeks, collecting 2 samples per week = 52 samples). 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 \$25.32 to \$66.05 per shipment or \$658.32 to \$1,717.3 for the six-month period (26 total weeks of shipment, with 2 samples included in each shipment).

If cyanobacteria screening results indicate microcystin-producing genes greater than five gene copies per microliter and concurrent weekly data for microcystins are not available for raw or finished water sampling points, the water systems must collect a sample at the finished water sampling point within twenty-four hours of notification of the detection. Initial sampling will likely be at an expedited 24-hr analysis cost if analysis is to be conducted by an outside laboratory, ranging from \$50 to \$270 (AVG. \$170) per sample [Table 1].

Off-season monitoring and analysis: Surface water systems may reduce monitoring to a minimum of one sample from each finished 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 \$50 to 100 (AVG \$82) per sample or \$650 to \$1,300 (AVG \$1,066). PWSs that have to ship samples to an outside laboratory would also have to pay for shipping at an estimated cost of \$25.32 to \$66.05¹ per shipment or \$329.16 to \$858.65 for the six-month period.

Increased microcystins monitoring to three days per week: The frequency of monitoring at finished water sampling points shall be increased to three days per week if microcystins are detected at finished water sampling points collected in accordance with this rule or distribution sampling points collected in accordance with this rule \$50 to \$100 (AVG \$82) per sample equating to \$150 to \$300 (AVG \$246) per week for the duration of increased sampling needs. Additional cost of public notification is included and accounted for in 3745-90-06 analysis.

Table 1: Lab Sample Processing Costs, 2020

Lab ID	Cost Microcystins , routine	Cost Microcystins , non-routine	24 hr expedited analysis (MC)	Cost qPCR
Lab 1	\$90	See 24 hour surcharge	200% surcharge, \$270/sample	\$140
Lab 2	\$75	\$150		NA
Lab 3	\$85			NA
Lab 4	\$100	See 24 hour surcharge	\$100	\$210
Lab 5	\$80		none	NA
Lab 6	\$75	\$135		NA
Lab 7	\$75		100% surcharge, \$150/sample	
Lab 8	\$85		No additional for expedited samples.	\$150
Lab 9	\$50-\$100		No additional for expedited samples (analysis depends on staff availability)	Sample cost depends on number samples. (\$50 standard)
Total Average Cost	\$82	\$163.75	\$170	\$143.75

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. Removal of the reporting violation issued in 3745-90-04(E) to public water systems and the requirement to issue a Tier 3 notification if results are not reported in accordance with 3745-89-08 will also result in decreased cost.

3745-90-05: This rule requires written treatment optimization protocols (with a minimum annual update) and/or a cyanotoxin general plan. The direct cost is primarily employee time spent or

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that of a professional engineer developing either or both, then reviewing and making any necessary changes to the treatment optimization protocol annually. 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 \$22,017.80 - \$110,089.00¹ (the cost associated with planning necessary for a substantial plant upgrade)

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. 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.

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 \$350 to \$ \$850 (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).

¹ U.S. Department of Labor, Bureau of Labor Statistics Inflation Calendar used to account for inflation from 2015 – 2020

17. 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

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by prompt detection and treatment of the most prevalent cyanotoxins created by harmful algal blooms.

Regulatory Flexibility

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

OAC rule 3745-90-03 allows for changes in monitoring frequency at the discretion of the director.

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.

19. 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.

20. 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.

The Drinking Water Assistance Fund (DWAF) has allocated potential monetary assistance through the 2021 Program Management Plan (PMP). Any portion of a planning, design, or construction loan that includes infrastructure improvements to address HAB or PFAS issues is eligible for a 0 percent interest rate for that portion. Ohio EPA intends to make up to \$50 million available at the discounted rate for this purpose.

For additional details on the Drinking Water Assistance Fund 2021 Program Management Plan, visit the Division of Environmental and Financial Assistance (DEFA) webpage at:

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<https://www.epa.state.oh.us/defa/>

The full DWAF PMP can be found here:

<https://epa.ohio.gov/Portals/29/documents/ofa/2021-DWAF-PMP-Compiled.pdf>

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