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Office of Water
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Final Technical Support Document:

Implementing the 2019 National Clean Water Act Section 304(a) Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin

Notice: This technical support document is primarily intended to support states, authorized tribes,[1] and territories (collectively referred to as "states and authorized tribes") in implementing the Environmental Protection Agency's (EPA) national Clean Water Act (CWA) Section 304(a) *Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins*[2] *and Cylindrospermopsin*.[3] States and authorized tribes may adopt one or both of the national CWA Section 304(a) recommended criteria into their state or tribal water quality standards (WQS) or may use the recommended criteria magnitude values as the basis for swimming advisories and related public notification purposes.

This document provides general information about the recommended criteria and flexibilities states and authorized tribes have, if implementing the criteria. The document also provides recommendations on how to assemble and interpret monitoring data, how to use monitoring data and other available information to make CWA Section 303(d) assessment determinations, and how to develop water quality management plans, including Total Maximum Daily Loads (TMDLs) and National Pollutant Discharge Elimination System (NPDES) permits, aimed at addressing nutrients as a precursor to cyanotoxin production.

While this document cites statutes and regulations that contain requirements applicable to these programs, it does not impose legally binding requirements on EPA, states, authorized tribes, other regulatory authorities, or the regulated community. EPA, states, authorized tribes, and other decision makers may adopt approaches on a case-by-case basis that differ from those provided in this document, as appropriate and consistent with statutory and regulatory requirements. Also, EPA may update this document as new scientific and technical information becomes available. In addition to this document, EPA has prepared the following information to support states and authorized tribes in their efforts to monitor and respond to cyanobacterial blooms and cyanotoxins in recreational waters:

- Cyanobacterial Harmful Algal Blooms in Water (website): https://www.epa.gov/cyanohabs
- Monitoring and Responding to Cyanobacteria and Cyanotoxins in Recreational Waters (website): https://www.epa.gov/cyanohabs/monitoring-and-responding-cyanobacteria-and-cyanotoxins-recreational-waters
- Recommendations for Cyanobacteria and Cyanotoxin Monitoring in Recreational Waters (PDF): https://www.epa.gov/cyanohabs/recommendations-cyanobacteria-and-cyanotoxin-monitoring-recreational-waters

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[1] "Authorized tribes" in this document generally refers to those federally recognized Indian tribes with authority to administer a CWA Section 303(c) WQS program. (Under EPA's regulations, a tribe that is eligible to administer WQS is likewise eligible to administer CWA Section 401 water quality certifications). When this document discusses CWA Section 402 implementation authority, "authorized tribes" refers to federally recognized Indian tribes with authority to administer a CWA Section 402 program. When this document discusses CWA Section 303(d) implementation authority, "authorized tribe" refers to federally recognized Indian tribes with authority to administer a CWA Section 303(d) program.

[2] Microcystins comprise a class of over 100 congeners and unless specified otherwise, "microcystins" refers to *total* microcystins.

[3] USEPA. 2019. *Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin 2019.* EPA 822-R-18-004. U.S. Environmental Protection Agency, Office of Water, Washington, DC. https://www.epa.gov/wqc/recommended-human-health-recreational-ambient-water-quality-criteria-or-swimming-advisories.

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General Questions about Recommended Cyanotoxin Water Quality Criteria

1. What are EPA's national CWA Section 304(a) recommended recreational water quality criteria for microcystins and cylindrospermopsin?

In 2019, EPA issued its national Clean Water Act (CWA) Section 304(a) recreational water quality criteria recommendations for two cyanotoxins, microcystins and cylindrospermopsin, reflecting the latest peer-reviewed scientific knowledge. The criteria are designed to protect the public from incidental exposure to harmful levels of these cyanotoxins while participating in water-contact activities in freshwater where immersion and incidental ingestion of water are likely. Such activities include, but are not limited to, swimming, water skiing, tubing, skin diving, water play by children, or similar water-contact activities in waterbodies designated for such recreational uses.[4] EPA issued its 2019 recommended criteria under the statutory authority of CWA Section 304(a).

EPA's 2019 recommended criteria for microcystins and cylindrospermopsin are summarized in Table 1, below. For more information on the magnitude, duration and frequency components of the criteria, see *Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin 2019* (Section 6).

Table 1. National CWA Section 304(a) Recommendations for Recreational Water Quality Criteria for Microcystins and Cylindrospermopsin[a]

Microcystins Magnitude (µg/L)	**Cylindrospermopsin Magnitude** (µg/L)	**Duration**	**Frequency**
8	15	1 in 10-day assessment period across a recreational season	Not more than 3 excursions in a recreational season in more than one year[b]

[a] States and authorized tribes can choose to adopt one or both criteria recommendations.

[b] An excursion is defined as a 10-day assessment period with any toxin concentration higher than the recommended criteria magnitude. When more than three excursions occur within a recreational season and that pattern reoccurs in more than one year, it is an indication the water quality has been or is becoming degraded and is not supporting its recreational use. As a risk management decision, states and authorized tribes should include in their WQS an upper-bound recurrence frequency stating the number of years that pattern can reoccur and still support its recreational use.

[4] For information about the scope and applicability of recommended recreational water quality criteria, see EPA's 2012 *Recreational Water Quality Criteria*, (Section 2.0 Applicability and Scope). Office of Water 820-F-12-058. https://www.epa.gov/sites/production/files/2015-10/documents/rwqc2012.pdf.

States and authorized tribes may adopt one or both of the national CWA Section 304(a) recommended criteria into their state or tribal water quality standards (WQS). Per WQS regulations at 40 CFR 131.20(a)[5], if a state or tribe chooses not to adopt water quality criteria for one or both of these cyanotoxins based either on EPA's recommendations or other scientifically defensible methods,[6] the state or authorized tribe must provide an explanation for not adopting such criteria as part of its triennial review.

EPA recognizes that multiple environmental factors can cause variability in algal bloom formation and toxin production, and that some years may produce blooms that occur for long periods, or blooms of shorter duration that occur repeatedly throughout a single recreational season, but such events may not occur every year. Therefore, EPA recommends that states and authorized tribes consider the pattern of excursions within a recreational season *and* across multiple years when determining whether the recreational use is attained.

The duration and frequency of cyanobacterial blooms can vary, with short-term blooms lasting days or weeks and long-term blooms lasting several months, or possibly all year. As a result, the frequency of excursions—defined as ten-day assessment periods during which time toxin concentrations have been measured above the recommended criteria magnitude—can also vary. States and authorized tribes that choose to adopt the national CWA Section 304(a) recommended criteria would analyze the pattern of excursions throughout the duration of each recreational season, and from one season to the next, as specified in state or tribal standards (see Question 3 for more on defining the length of a recreational season). For example, a 90-day recreational season with one ten-day excursion each month is a different pattern than a 90-day recreational season with three consecutive ten-day excursions in the final month of the recreational season. An understanding of the patterns of blooms can help waterbody managers respond effectively to protect public health. The recommended criteria components listed in Table 1, above, can help to identify a short- or long-term temporal trend or a spatial distribution pattern of cyanotoxin excursions that can be used to evaluate a waterbody (see Question 8, which provides detail on how to count excursions within a recreational season).

EPA recommends that when more than three excursions occur within a recreational season *and* a pattern (of more than three excursions per recreational season) reoccurs in more than one year, it is an indication that the water quality is or may be becoming degraded such that the waterbody no longer supports its recreational use. It is important to note that a pattern of more than three excursions per recreational season would not need to be *the same* pattern each year (e.g., the pattern of multiple excursions may resemble a long-term bloom of back-to-back excursions one year and several discrete, short-term excursions another year). A determination of whether the waterbody supports its recreational use would depend on the number of years when multiple cyanotoxin excursions are observed with respect to the *recurrence frequency*, which is specified by the state or authorized tribe that adopts the criteria. It is also important to note that the years with multiple excursions do not have to be consecutive to indicate a water quality problem. The recurrence frequency is a risk management decision that states and authorized tribes need to determine when developing their WQS. States and authorized tribes may make different risk management decisions for different types of waterbodies but should specify in their

[5] 40 CFR 131.20(a): "… if a State does not adopt new or revised criteria for parameters for which EPA has published new or updated CWA section 304(a) criteria recommendations, then the State shall provide an explanation when it submits the results of its triennial review to the Regional Administrator consistent with CWA section 303(c)(1) and the requirements of paragraph (c) of this section."

[6] 40 CFR 131.11(b)(iii)

adopted criteria the number of years a pattern of multiple (i.e. more than three) cyanotoxin excursions per recreational season can occur for the recreational use to be supported (see Example 1 text box in Question 3).

2. How can EPA's recommended recreational water quality criteria values for microcystins and cylindrospermopsin be used for swimming advisories?

When a bloom or the presence of cyanotoxins is confirmed, the recreational waterbody manager typically issues a public notification (either a swimming advisory or a closure of swimming areas) to raise awareness of the potential risks associated with contact with the cyanobacterial bloom or its toxins in recreational waters. Swimming advisories are recommendations to limit swimming or other recreational water-contact activities, due to an increased health risk from contact with or ingestion of the cyanobacteria or cyanotoxins; whereas, a closure notification or posting typically means that the waterbody is officially closed to the public.

EPA envisions that if states or authorized tribes decide to use the recommended criteria magnitude values for swimming advisory purposes, they can manage a cyanotoxin monitoring and advisory program in the same way as they manage any existing recreational water advisory program (e.g., those for pathogen indicators, like *E. coli* or enterococci).[7] States and authorized tribes may choose to apply either or both recommended criteria magnitude values as the basis for public notifications (i.e., swimming advisories or closures) at recreational waterbodies. EPA's swimming advisory recommendations for microcystins and cylindrospermopsin are summarized in Table 2, below.

Table 2. Swimming Advisory Recommendations for Microcystins and Cylindrospermopsin[a]

Microcystins Magnitude (µg/L)	Cylindrospermopsin Magnitude (µg/L)	Duration	Frequency
8	15	One day	Not to be exceeded

[a] States and authorized tribes can choose to apply one or both recommended magnitude values as the basis for swimming advisories.

The guidelines for posting an advisory or closure for a waterbody are typically set at the state, tribal, or local level.[8] EPA recognizes that some states and authorized tribes may handle swimming advisories through their health departments and not through their environmental quality departments. As a result, inter-departmental coordination may be helpful to implement an advisory program which can also serve to inform drinking water providers and water quality practitioners. EPA has provided an example Cyanobacteria Bloom Response Contact List on its website to help state or tribal employees consider who to contact in the event of a cyanobacterial bloom (see: https://www.epa.gov/sites/production/files/2017-07/contact-list-rec-water.docx).

[7] Note, however, that monitoring, reporting and notification of potential exposure to cyanobacteria and their toxins in coastal recreation waters cannot be funded under the BEACH Act Grant program.

[8] We use the term, "jurisdictional level" to include state or tribal. See *Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin 2019* (Appendix B), which summarizes available information on state recreational water guidelines for cyanotoxins and cyanobacteria.

If using EPA's swimming advisory recommendations for a swimming advisory or a closure, EPA recommends that the relevant authority (typically a local health department official or water quality management official) notify the public whenever the concentration of microcystins or cylindrospermopsin in a sample is higher than the recommended criteria magnitude value. EPA also recommends that a swimming advisory not be lifted until at least two subsequent samples, taken at least 24 hours apart, show that the toxin concentration has fallen below the recommended magnitude value of the criteria. States and authorized tribes may choose to extend the re-sampling period after issuing a swimming advisory over several days, to allow for additional photodegradation of the cyanotoxin.[9] The important point is to wait until the concentration of microcystins or cylindrospermopsin subsides below the recommended swimming advisory magnitude values before the swimming advisory is lifted. By increasing the monitoring frequency at a site where a swimming advisory is issued, recreational waterbody managers will get a clearer understanding of the temporal nature of toxins which can be useful in making management decisions to protect the recreational use, including when to remove an advisory.

EPA has published materials to help recreational waterbody managers responsible for monitoring and responding to cyanobacterial blooms. These materials include customizable infographics and a communication toolbox with examples of public messages, press releases, and signage that recreational waterbody managers may use to inform the public of increased health risks associated with exposure to harmful algal blooms (HABs), or cyanobacteria, and their toxins. In addition, EPA has provided recommendations for waterbody managers (or relevant state, local or tribal officials) regarding various water monitoring, sampling, and testing methods. These recommendations can help waterbody managers determine whether a cyanobacterial bloom is producing toxins, whether the bloom presents an increased health risk to water-contact recreators, and whether immediate actions should be taken to notify the public if a closure is recommended based on waterbody test results. For more information, follow these links:

- Infographics to Help Educate the Public on HABs Basics: https://www.epa.gov/cyanohabs/infographics-help-educate-public-habs-basics
- Communicating about Cyanobacterial Blooms and Toxins in Recreational Waters: https://www.epa.gov/cyanohabs/communicating-about-cyanobacterial-blooms-and-toxins-recreational-waters
- Monitoring and Responding to Cyanobacteria and Cyanotoxins in Recreational Waters: https://www.epa.gov/cyanohabs/monitoring-and-responding-cyanobacteria-and-cyanotoxins-recreational-waters

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[9] For studies that demonstrated cyanotoxin breakdown in natural waters within a week, see:

1. Chiswell, R., Shaw, K., and Eaglesham, G.R. 1999. *Stability of cylindrospermopsin, the toxin from the cyanobacterium Cylindrospermopsis raciborski, effect of pH, temperature, and sunlight on decomposition*. Environmental Toxicology. 14:155-161.
2. Jones, G.J., Blackburn, S. I., and Parker, N.S. 1994. *A toxic bloom of Nodularia spumigena Mertens in Orielton Lagoon, Tasmania*. Australian Journal of Marine and Freshwater Research. 45:787-800.

3. **What flexibilities do states and authorized tribes have if they adopt the recommended recreational water quality criteria for microcystins and cylindrospermopsin?**

If states or authorized tribes choose to adopt EPA's national CWA Section 304(a) *Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin*, several flexibilities are available to accommodate specific water quality-related circumstances while meeting the requirements of the CWA and EPA's WQS regulation.[10] In addition to considering the Agency's national recommended water quality criteria when revising their WQS, states and authorized tribes may adopt, where appropriate, other scientifically defensible criteria that differ from EPA's recommendations. For example, states and authorized tribes can:

- *Define the length of the recreational season.* States and authorized tribes can adopt seasonal designated uses of a waterbody with respect to various CWA Section 304(a) recommended criteria, including the recommended criteria for microcystins and cylindrospermopsin. For states and authorized tribes that have adopted seasonal uses, the recommended cyanotoxin criteria would apply only to the primary contact recreational season.[11] The length of a "recreational season" is an important consideration because states and authorized tribes would likely monitor the quality of their highest-priority recreational waters throughout the recreational season. For purposes of establishing seasonal WQS, a change to the recreational season constitutes a change to the state's or authorized tribe's designated use in their WQS and would need to be reviewed and approved by EPA pursuant to CWA Section 303(c). Because local health departments or departments of parks and recreation may define the recreational seasons for inland waterbodies, it is important for states and authorized tribes to coordinate with these local authorities when identifying the length of the state's or tribe's recreational season in WQS.
- *Prioritize waterbodies for monitoring.* EPA recommends that states and authorized tribes prioritize their waterbodies, for monitoring purposes, based on risk factors relevant to the likelihood of a cyanotoxin or HAB event and its relative impact to recreational users of each waterbody. Prioritizing which waterbodies to monitor can help to direct limited resources where they will be most effective (for more on prioritizing waterbodies for monitoring, see Question 6). For all recreational waterbodies—especially for those that are lower priority for monitoring—EPA also recommends that states and tribes communicate with their constituents about how to identify and report a potential cyanobacterial bloom (for templates and other communication tools, see Question 2).
- *Define a recurrence frequency.* The recommended criteria for microcystins and cylindrospermopsin recommend that the toxin concentrations should not be above the recommended criteria magnitude values in more than three 10-day periods per recreational season *in more than one year*, but the recommended criteria do not specify an upper-bound number of years that pattern can occur across recreational seasons (i.e., a recurrence frequency). This provides states and authorized tribes the flexibility to define what the recurrence frequency should be for their state or tribe. The recurrence frequency can be thought of as a sliding window of time during which patterns of excursions should be considered. For example, some states or authorized tribes might assess the pattern of excursions over a rolling 3-year period while others may choose to count over a rolling 5-year period, or longer. EPA recommends that each state or

[10] 40 CFR Part 131 – Water Quality Standards.

[11] 40 CFR 131.10(f) specifies that states and authorized tribes "may adopt seasonal uses as an alternative to reclassifying a waterbody or segment thereof to uses requiring less stringent water quality criteria."

authorized tribe documents the recurrence frequency in the state or tribal water quality standards or supporting documents. Example 1, below, provides sample text that a state or authorized tribe could include in its adopted criteria to specify the recurrence frequency. EPA encourages states and authorized tribes to explain their selection of recurrence frequency to their constituents when they put their draft standards out for public comment.

Example 1: Written Statement to Specify Recurrence Frequency

If a state or authorized tribe chooses to adopt the recommended criteria, EPA expects the state or tribe to also include the recurrence frequency in its WQS. A state or authorized tribe may achieve this with a written statement in its standards. An example written statement could say, *"The concentration of microcystins shall not exceed 8 µg/L in more than three 10-day periods per recreational season, for more than one recreational season, over a rolling 5-year period."*

- *Determine how to delineate the 10-day assessment period.* States and authorized tribes have flexibility in applying the 10-day assessment period. Some may choose to use predetermined 10-day assessment periods for waterbodies with a documented history of cyanobacterial blooms or cyanotoxin production (e.g., the month of June could have three 10-day assessment periods). Another approach is to begin the 10-day assessment period in response to a visible bloom that has been confirmed as toxin-producing. States and authorized tribes are encouraged to consider the application of the frequency and duration components to capture elevated toxin concentrations (which may or may not coincide with the general proliferation of total cyanobacteria at high densities). More information on delineating assessment periods throughout a recreational season is provided in Question 8.
- *Derive site-specific criteria elements*. States and authorized tribes may modify EPA-recommended criteria to fit their unique situation, based on site-specific data and information, pursuant to 40 CFR 131.11(b)(ii). For example, a state or tribe may derive site-specific criteria based, in part, on information about the exposure variables among the population that uses the waterbody (e.g., age and incidental ingestion rates) or to take into account specific cultural or land use practices at or near the site. The site-specific criteria must be based on sound scientific rationale and protective of the designated use of the state's or tribe's waterbodies pursuant to 40 CFR 131.11(a) and approved by EPA pursuant to Section 303(c) of the CWA.
- *Revise the designated uses of waterbodies within their state*. Pursuant to 40 CFR 131.10(g), states and authorized tribes may remove a designated CWA Section 101(a)(2) use,[12] which is not an existing use, if the state can demonstrate that attaining the designated use is not feasible because one of the attainability factors listed in 40 CFR 131.10(g) is met. The decision to remove a designated CWA Section 101(a)(2) use (e.g., primary contact recreation use) or a sub-category of such a use, or to designate a subcategory of such a use that requires less stringent criteria, must be based on an appropriate use attainability analysis, pursuant to 40 CFR 131.10(j). Additionally, revisions to designated uses are considered a change to water quality standards that must include documentation to support the use revision pursuant to 131.10 and 131.20 and are subject to

[12] CWA Section 101(a)(2) uses are those that provide for the protection and propagation of fish, shellfish, and wildlife, and recreation in and on the water, as well as for the protection of human health when consuming fish, shellfish, and other aquatic life (e.g. recreation use, aquatic life use).

public participation requirements of 40 CFR 131.20(b) and to EPA's review and approval under CWA Section 303(c).[13]

- *Adopt a WQS variance.* A state or authorized tribe could adopt, and EPA could approve, a WQS variance in cases where the recreational use and associated criterion (microcystins or cylindrospermopsin, as translated to nutrients) are unattainable in the near-term, but it is possible to make feasible progress toward attaining that designated use and criterion.[14] For information on the connection between cyanotoxins and nutrients, see Question 16. For information on translating between microcystins and nutrient loads in lakes, see Question 17 and Question 18.

4. What is the relationship between cyanobacterial cell density and the recommended criteria?

EPA recognizes that some states and authorized tribes have included total cyanobacterial cell density values as an important part of their HAB management strategy. EPA did not recommend criteria based on cyanobacterial cell density because of the uncertainties quantifying the relationship between cell densities and observed health effects. Available information on cell density, health endpoints, and guidelines developed by other authorities on total cyanobacteria cells is described in the Effects Characterization section (Section 7.5) and in Appendix D of the national CWA Section 304(a) recreational water quality criteria recommendations for microcystins and cylindrospermopsin. EPA presents a toxigenic cell number based on the number of toxigenic cells that could produce microcystins equivalent to the recommended criteria magnitude. The Effects Characterization section also describes gene-based detection methods (i.e., quantitative polymerase chain reaction (qPCR)) that can target and quantify the toxigenic subpopulation of cyanobacteria that are present in a waterbody and used in some states or authorized tribes (see Section 7 of the national CWA Section 304(a) recreational water quality criteria recommendations for microcystins and cylindrospermopsin).

The presence of cyanobacteria does not necessarily mean that cyanotoxins are being produced, and conversely, cyanotoxins can be present at levels above the recommended criteria magnitude when accumulations of cyanobacteria were not observed.[15] Additionally, benthic cyanobacteria, occurring at the bottom of the waterbody, may not be visible from the surface, but may still produce toxins.

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[13] USEPA. 2006. *Use Attainability Analyses and Other Tools for Managing Designated Uses* 821-R-07-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC..

[14] The WQS Variance Building Tool is designed to help states, territories, and authorized tribes determine whether a WQS variance is an appropriate tool for a particular situation. For more information, see: https://www.epa.gov/wqs-tech/water-quality-standards-variance-building-tool.

[15] See *Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin*, Section 3.3.2 Persistence.

5. What are the potential health effects of cyanotoxin exposure to humans, pets and livestock?

EPA's national CWA Section 304(a) recommended criteria for microcystins and cylindrospermopsin reflect the latest scientific knowledge on the potential human health effects from recreational exposure to these two cyanotoxins.[16] Potential human health effects from recreational exposure to cyanobacteria and these two cyanotoxins could range from gastrointestinal illnesses to liver and kidney damage. For information on the health effects of exposure to microcystins and cylindrospermopsin to humans, go to:

- Health Effects Support Document for the Cyanobacterial Toxin Microcystins
- Health Effects Support Document for the Cyanobacterial Toxin Cylindrospermopsin

Although the recommended recreational criteria values are for the protection of human health (not pets and livestock), common signs of cyanotoxin poisonings in pets and livestock may include repeated vomiting, diarrhea, loss of appetite, abdominal swelling, stumbling, seizures, convulsions, disorientation, inactivity, or skin rashes and hives, and in extreme cases collapse and sudden death. For more information on concerns relating to pet or livestock exposure to microcystins and cylindrospermopsin, including a summary of guidelines that several states or authorized tribes have developed, go to:

- Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin (Section 7.8 Livestock and Pet Concerns)
- Learn more about how to protect your dog (Protect Your Pooch: How to keep your dog safe from toxic algae)

In addition to the EPA resources listed above, the Centers for Disease Control and Prevention (CDC) provides multiple resources, such as frequently asked questions (FAQs), Veterinarian Cards and Animal Safety Alerts, to help educate the public of the dangers associated with cyanotoxin exposure to pets. The CDC suggests that pet owners prevent their animals from playing in—or drinking—scummy water. If a dog has been swimming in scummy water, the CDC recommends rinsing them off immediately to prevent the dog from licking cyanobacteria off their fur. The CDC also collects voluntarily reported data on individual human and animal cases of illnesses from HAB-associated exposures through its One Health Harmful Algal Bloom System.[17]

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[16] Although accumulations of cyanobacterial cells have been associated with outbreaks of inflammatory illness (e.g., rashes) unrelated to the production of cyanotoxins, available data are insufficient to develop recreational values for a total cyanobacterial cell density related to inflammatory health endpoints among humans.

[17] https://www.cdc.gov/habs/ohhabs.html

Implementation Questions about Monitoring, Assessment and Listing

6. What information should states and authorized tribes consider when prioritizing which waterbodies to monitor based on risk of elevated levels of cyanotoxins?

EPA recommends that states and authorized tribes prioritize their waterbodies, for monitoring purposes, based on an objective set of risk factors relevant to the likelihood of a cyanotoxin or HAB event and its relative impact to recreational users of each waterbody. Prioritizing which waterbodies to monitor can help to direct often limited resources where they will be most effective. It is important that a prioritization process is transparent, does not create inequities to vulnerable populations, and works to ensure that waterbodies with high recreational use and likelihood of having algal blooms are prioritized.

States and authorized tribes are encouraged to collaborate with a range of state, tribal and local agencies, waterbody managers and citizen science/volunteer monitoring organizations to monitor local waterbodies. By leveraging the presence of local resources to monitor, states and authorized tribes can more effectively coordinate risk management and response activities. For example, a local recreational waterbody manager who is collecting weekly samples for other indicators may be able to collect an additional sample for cyanotoxins. CWA practitioners, public health officials, and other waterbody managers may consider a variety of information when prioritizing which waterbodies to monitor for potential cyanotoxins. Some of the risk factors listed below may help state, tribal and local officials to identify which waterbodies are most vulnerable:

- the type of waterbody and numbers of recreational users (e.g., is it a public swimming area?);
- past/historical occurrence of cyanotoxin producing blooms;
- seasonal patterns of cyanobacterial blooms (influenced by temperature and precipitation, among other factors);
- point and nonpoint sources of nutrients in the waterbody and in the watershed;
- physical and hydrologic factors (e.g., depth, fetch[18], light attenuation, availability of organic matter, turbidity, temperature, pH);
- chlorophyll-a and phycocyanin[19] levels (i.e., cell densities);
- other water quality limitations or impairments; and,
- any other information gathered as part of source water assessments or sanitary surveys.

Some states and authorized tribes use screening tools to determine which waterbodies to prioritize for cyanotoxin sampling. They may look at related data such as cyanobacteria or phytoplankton data collected as part of their monitoring program. States and authorized tribes may consider using field test kits to screen for waters with elevated toxins before collecting a sample for laboratory analysis. Another screening tool based on satellite imagery is the Cyanobacteria Assessment Network (CyAN). EPA's Office of Research and Development developed the CyAN Mobile Application for the early detection of select algal blooms (those containing phycocyanin) in U.S waterbodies and freshwater lakes over one sq km in size to help local and state water quality managers make faster and better-informed management

[18] Fetch refers to the area of a lake surface over which the wind blows in an essentially constant direction, thus generating waves. The term also is used as a synonym for fetch length, which is the horizontal distance over which wave-generating winds blow.

[19] Phycocyanin is a pigment present in cyanobacteria. Sensors are available which measure the presence of this pigment and report relative cyanobacteria concentrations in cells/mL.

decisions related to cyanobacterial blooms. It provides an easy-to-use, customizable interface for accessing algal bloom satellite data for over 2,000 of the largest lakes and reservoirs in the United States. The CyAN app is free and available for download in the Google Play™ store for Android™ devices, and a web-based version of the app is currently being developed. [20]

Reporting data on cyanobacterial blooms and toxin levels can improve transparency with the public and help to provide a regional or national understanding of where blooms are taking place. Some states and authorized tribes have reported microcystins data through the Water Quality Portal, an interagency website that provides public access to water quality data collected by over 400 federal, state, tribal and local agencies .[21] Anytime states are monitoring water quality and whenever authorized tribes or other organizations are using EPA grant money to perform water quality monitoring, they are required, as part of their grant terms and conditions, to upload their data to the Water Quality Portal. The Portal is one of many sources of information which may inform states and authorized tribes when taking a risk-based approach to prioritizing recreational waterbodies for monitoring.

Additional materials to assist recreational waterbody managers interested in monitoring for and responding to cyanobacteria and cyanotoxins in recreational waters are listed below:

- Monitoring and Responding to Cyanobacteria and Cyanotoxins in Recreational Waters.
- Recommendations for Cyanobacteria and Cyanotoxin Monitoring in Recreational Waters (PDF).
- Field and Laboratory Guide to Freshwater Cyanobacteria Harmful Algal Blooms for Native American and Alaska Native Communities: This 2015 guide, produced by the USGS, provides field images to help differentiate between cyanobacterial blooms (some of which produce toxins), non-toxic algal blooms, and floating plants that might be confused with algae.
- EPA Sanitary Survey App for Marine and Fresh Waters: EPA has updated its recreational sanitary survey app, *EPA Sanitary Survey App for Marine and Fresh Waters*, to help waterbody managers evaluate all contributing waterbody and watershed information including water quality data, pollution source data, and land use data. The updated app enables jurisdictions to easily gather

[20] Methods to assess bloom temporal frequency, spatial extent, magnitude, and lake occurrence with satellite data have been developed. The 300-meter resolution Sentinel-3 satellites capture less than 1% of waterbodies and approximately 33% of drinking water intakes but provide frequent monitoring and can readily identify cyanobacterial HABs. Therefore, CyAN assessment methods can be applied at a national scale but are limited to the largest lakes. Satellites with 10 to 30 m resolution, such as Landsat and Sentinel-2, can capture 62% of lakes greater than 1 ha (2.47 acres) and 95% of the lakes with public drinking water intake locations. These satellites make less frequent flyovers and are not as well equipped with sensors to easily distinguishing cyanobacterial HABs from other types phytoplankton. For more information, see:

1. Urquhart et al. *A method for examining temporal changes in cyanobacterial harmful algal bloom spatial extent using satellite remote sensing*. Harmful Algae, 67 (2017), pp. 144-152. https://doi.org/10.1016/j.hal.2017.06.001

2. Clark et al. *Satellite monitoring of cyanobacterial harmful algal bloom frequency in recreational waters and drinking water sources*. Ecological Indicators, 80 (2017), pp. 84-95. https://doi.org/10.1016/j.ecolind.2017.04.046.

3. Stumpf et al. *Challenges for mapping cyanotoxin patterns from remote sensing of cyanobacteria*. Harmful Algae, 54 (2016), pp. 160-173. https://doi.org/10.1016/j.hal.2016.01.005.

[21] Visit the Water Quality Portal here: https://www.waterqualitydata.us/. For help uploading data to the Water Quality Portal through the Water Quality Exchange (WQX), phone 1-800-424-9067, e-mail STORET@epa.gov, or visit https://www.epa.gov/waterdata/support-storage-and-retrieval-and-water-quality-exchange-data-owners.

information on possible existence of harmful algal blooms, in addition to likely sources of bacterial pollution.

7. How frequently and over what time period should states and authorized tribes monitor cyanotoxin levels?

States and authorized tribes have discretion and flexibility when establishing a monitoring program for cyanotoxins. For example, baseline monitoring could include routine monitoring (e.g., weekly monitoring over the course of a recreational season), responsive/episodic monitoring (e.g., initiating sampling in response to a physical bloom or reported potential negative health impact to animals or humans), or a combination of the two. EPA recommends that states and authorized tribes use their monitoring strategy or annual workplans to identify the monitoring approach that will be implemented for the recreational season, considering available resources and the potential use of tools, such as remote sensing and citizens' volunteer monitoring.

EPA recommends more frequent sampling if a bloom is detected, particularly if it is documented to have toxin levels above the recommended criterion magnitude. That is, once a concentration higher than the criterion magnitude is detected, a state or authorized tribe with a biweekly or responsive sampling program should switch to more frequent sampling (e.g., weekly or daily) until the bloom subsides or the cyanotoxin concentrations are no longer above their respective cyanotoxin criteria magnitude levels. Once the cyanotoxins have subsided, EPA recommends that regular monitoring of prioritized waterbodies continue for the duration of the recreational season. EPA also recommends that states and authorized tribes consider doing follow up monitoring at these sites in subsequent years to capture the recurrence frequency.

For more information about monitoring for cyanotoxins, see EPA document, Recommendations for Cyanobacteria and Cyanotoxin Monitoring in Recreational Waters.

8. How should states and authorized tribes analyze and interpret cyanotoxin monitoring data and information to evaluate ambient conditions and recreational use support?

The recommended 10-day duration component of the criteria naturally translates into the use of 10-day assessment periods over the course of a recreational season to evaluate ambient waterbody conditions and recreational use attainment.

The sampling frequency (daily, weekly, biweekly, etc.) is a risk-management decision made at the state, tribal, or local level. Weekly monitoring may provide two samples within the 10-day assessment period, or weekly monitoring may provide data for two consecutive 10-day assessment periods (depending on how the weeks and 10-day periods align). If one or more samples are collected within the 10-day assessment period that are above the criteria magnitude, these should be counted as a single excursion. EPA recognizes other sampling schedules may be used as long as they take into consideration the need to be protective of recreational use of the given waterbody.

States and authorized tribes have flexibility delineating the 10-day assessment periods within their recreational season. Example 2 text box, below, is provided to illustrate how samples with concentrations above the criterion magnitude can count towards excursions when assessing use attainment. For the application of these criteria, an excursion is defined as a 10-day assessment period during which time monitoring data shows a concentration of microcystins or cylindrospermopsin that is higher than the recommended magnitude value. When more than three excursions occur within a recreational season and a pattern of excursions reoccurs for more than one year within the recurrence frequency (described in Question 3), the criterion is exceeded (i.e., the waterbody would be considered impaired).

The calendar figures in Example 2 illustrate two ways states and authorized tribes could set up their 10-day assessment periods, either by blocking out 10-day periods before the start of the recreational season (Example 2A) or by marking 10-day assessment periods from the date a bloom is detected and an excursion is confirmed (Example 2B). Once an approach to delineating 10-day assessment periods is selected, the same approach should be used each year.

Example 2: Examples of How a State or Tribe Might Delineate Assessment Periods

The following examples are intended to demonstrate how the number of excursions can be counted within a given recreational season. The red X shown on the example calendars denotes days when cyanotoxin monitoring results were *above* the recommended cyanotoxin criteria magnitude, and the blue check denotes days when monitoring results that were *below* the recommended cyanotoxin criteria magnitude. The shaded boxes represent 10-day assessment periods. A 10-day assessment period with one or more measured cyanotoxin concentrations above the criteria magnitude is counted as an excursion. Boxes without any shading, in Example 2B, represent days that are not included in a 10-day assessment period (because no recent bloom was observed).

Example 2A: Predetermined 10-Day Assessment Periods

June/July

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
✓ 1	2	3	4	5	6	7
✓ 8	9	10	11	12	13	14
X 15	16	17	18	19	20	21
✓ 22	23	24	25	26	27	28
X 29	30	1	2	3	4	5
✓ 6	7	8	9	10	11	12

Example 2A. In this example, the state or authorized tribe establishes a predetermined weekly monitoring schedule to begin on June 1 and has delineated consecutive 10-day assessment periods throughout the recreational season. On June 1, June 8, June 22, and July 6, weekly monitoring results showed a cyanotoxin concentration below the recommended criteria magnitude. However, monitoring results from June 15 and June 29 showed concentrations above the recommended criteria magnitude, resulting in two excursions in the month of June because the cyanotoxin concentrations were detected above the recommended criteria magnitude during two separate 10-day assessment periods.

Example 2B: Responsive 10-day Assessment Periods

June/July

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4	5	6	7
8	9	10	11	12 X	13	14
15	16	17	18	19 ✓	20	21
22	23	24	25	26	27	28
29 X	30	1	2	3	4	5
6 ✓	7	8	9	10	11	12

Example 2B. In this example, the state or authorized tribe monitors for cyanotoxins *in response to* a suspected bloom, once the monitoring data indicates a concentration of microcystins or cylindrospermopsin that is higher than the recommended criteria magnitude. On June 12, the first suspected bloom of the season was sampled and confirmed when monitoring results showed a cyanotoxin concentration above the recommended criteria magnitude. This started the 10-day assessment period and a sample taken one week later, on June 19th, showed that the cyanotoxin levels had subsided. Again, on June 29th, a suspected bloom was sampled and confirmed, triggering the start of a new 10-day assessment period (through July 8th). Once again, a sample taken one week later, on July 6th, showed that the cyanotoxin levels had subsided. (Note: If the sample on July 6th showed toxin concentrations above the recommended criteria magnitude, a new 10-day assessment period would begin on July 9th.) The measures above the recommended criteria magnitude equate to two 10-day excursions because the elevated cyanotoxin concentrations were detected across two separate 10-day periods. Response-based monitoring may be a better option for local jurisdictions with limited monitoring resources.

9. What should states and authorized tribes consider when selecting an analytical method?

States and authorized tribes may choose an analytical method that they deem appropriate for monitoring and assessment purposes. When selecting a method to monitor for microcystins or cylindrospermopsin, states and authorized tribes should consider cost and practicality of various monitoring methods, and reliability and comparability of results, among other factors. Well over 100 microcystin congeners are known to exist; however, the majority of toxicological data on the effects of microcystins are available for microcystin-LR (a frequently monitored congener). Therefore, EPA established its recommended criterion for microcystins based on microcystin-LR and used it as a surrogate for other microcystin congeners.

Analytical methods should be sufficiently sensitive to detect the cyanotoxins in question at concentrations below the recommended criteria magnitude; however, analytical results may vary depending on the analytical methods used.

Methods vary widely in sensitivity, rapidity, cost, and ease of use. As described below, there are both rapid screening tests and laboratory methods used to detect and identify cyanobacterial cells; determine the presence, absence, or count of individual congeners; or measure the concentration of total cyanotoxins in a water sample. It may be cost effective to use field test kits at several locations throughout a waterbody prior to selecting samples for lab-based analysis (see below for description of field test kits). Some analytical methods measure the sum of all congeners while other methods measure specific congeners of interest. Methods that measure more congeners provide a more complete assessment of potential public health risk, while methods that identify specific congeners can be helpful to understand specific characteristics of the bloom. Each method has specific requirements for sample preparation/processing and analytical standards. These should also be considered when planning a monitoring program.

EPA does not require any single method to monitor for cyanotoxins. Analytical methods should be sufficiently sensitive with minimum detection levels lower than the recommended criteria magnitude of microcystins and cylindrospermopsin. In addition to the list below, EPA refers readers to the National Environmental Methods Index (https://www.nemi.gov/home/) for information on analytical methods. Also, the Interstate Technology and Regulatory Council Harmful Cyanobacterial Blooms project team has included a comprehensive summary of analytical methods and a method selection tool on its website (https://www.itrcweb.org/Team/Public?teamID=82).

Methods for quantifying cyanotoxins (total or individual congener concentrations) include, but are not limited to:

- EPA developed standardized methods for analyzing cyanotoxins in ambient and drinking water:
    - EPA Method 544, a standardized, single laboratory validated liquid chromatography/tandem mass spectrometry (LC/MS/MS) method for the detection of microcystins and nodularin in drinking water;
    - EPA Method 545, a standardized, single laboratory validated LC/MS/MS method for the detection of cylindrospermopsin and anatoxin-a in drinking water; and
    - EPA Method 546, a standardized, single laboratory validated method using an Adda enzyme-linked immunosorbent assay for the detection of microcystins and nodularin in ambient and drinking water.
- Lab-based Enzyme-Linked Immunosorbent Assay (ELISA) method. The ELISA method is typically run with only a microcystin-LR standard for comparison but can quantify a broad range of microcystin congeners (especially if using an ADDA-based antibody).
- Field test kits (e.g., Eurofins Technologies (formerly Abraxis) test strip, Envirologix QualiTube). These field-based methods do not require laboratory instrumentation and can produce semi-quantitative results within about an hour; however, these methods may be better suited for screening purposes, given their limited range of quantification.
- High performance liquid chromatography (HPLC) combined with ultraviolet/photodiode array detectors (UV/PDA). This method requires known toxin standards to be run alongside the water sample(s) to quantify the toxin concentration(s), and its results are limited to only those congeners for which standards are available and analyzed. HPLC-UV/PDA methods are based on a non-selective detector and co-eluting interferents can prevent accurate identification of components and quantitation. It is less sensitive than mass spectrometry methods (see below).

- Liquid chromatography/tandem mass spectrometry (LC/MS/MS).[22] Like HPLC-UV/PDA, this method requires known toxin standards to be run alongside the water sample(s) to quantify the toxin concentration(s) and its results are limited to only those congeners for which standards are available and analyzed. It is, however, the most precise method for quantitation of analytes (such as specific microcystin congeners) if standards are available. This method may also require the use of solid phase extraction for analytes with weak product ion abundance (microcystins). The LC-MS/MS MMPB (2-methyl-3(methoxy)-4-phenylbutyic acid) method analyzes the chemically cleaved ADDA group common to all microcystin congeners and therefore provides an alternative LC-based approach for analyzing a broad range of microcystin congeners. The MMPB method may also detect microcystins break-down products and could potentially overestimate microcystin concentrations in some settings.
- Protein phosphatase inhibition assay (PPIA). This method has varying degrees of specificity depending on its substrate composition and may react to compounds in the sample other than microcystins.[23]

EPA recognizes that several states or authorized tribes may monitor for cyanobacterial cell densities in addition to, or in lieu of, monitoring for cyanotoxins. Laboratory-based methods for quantifying cyanobacterial cells include microscopy and quantitative polymerase chain reaction (qPCR) and microarrays/DNA chips. Field-based methods include, but are not limited to, remote sensing based on satellite imagery, FlowCam (imaging particle analysis), flow cytometry, and derivative spectrophotometry. For more on the relationship between cell densities and the recommended criteria, see Question 4.

10. What should states and authorized tribes consider when selecting sampling locations?

Like other aspects of a monitoring program, decisions on sample location are guided by the management questions being addressed. For example, when monitoring recreational waters for public health protection, it’s reasonable to target sample collection toward capturing the highest potential exposure risks; therefore, EPA recommends that states and authorized tribes collect single grab samples from designated swimming areas, near the shoreline, or a composite of samples taken at the same time from points within the splash zones where children play (e.g., ankle-, knee- and chest-deep). EPA does not recommend averaging sampling data taken at different times because averaging data over time does not give a clear picture of the pattern of cyanobacterial bloom formation and cyanotoxin exposure to the population using the waterbody for recreational purposes. For example, states should not average data collected over different days in a ten-day assessment period.

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[22] For more information on single laboratory validated methods for detecting cyanotoxins in freshwaters by LC/MS/MS, see (1) https://www.epa.gov/water-research/single-laboratory-validated-method-determination-cylindrospermopsin-and-anatoxin to detect cylindrospermopsin and anatoxin-a, and (2) https://www.epa.gov/water-research/single-laboratory-validated-method-determination-microcystins-and-nodularin-ambient to detect microcystins and nodularin (combined intracellular and extracellular).

[23] Jarkko Rapala, Kirsti Erkomaa, Jaana Kukkonen, Kaarina Sivonen, Kirsti Lahti. *Detection of microcystins with protein phosphatase inhibition assay, high-performance liquid chromatography–UV detection and enzyme-linked immunosorbent assay: Comparison of methods*, Analytica Chimica Acta, Volume 466, Issue 2, 2002, Pages 213-231, ISSN 0003-2670, https://doi.org/10.1016/S0003-2670(02)00588-3.

When collecting samples, it is essential to establish and follow quality assurance (QA) and quality control (QC) procedures. EPA has created guidance for producing quality assurance project plans (QAPP) to aid in documenting quality assurance/quality control (QA/QC) procedures.[24] It is recommended that a QAPP be in place for monitoring programs to assure the quality of the resulting data and the appropriateness of their use. Detailed procedures for collecting, handling, and analyzing samples are typically specified in the field standard operating procedures (SOPs) and analytical methods SOPs.[25]

SOPs may also be informed by sample collection and handling procedures established by the laboratory performing sample analysis. For example, a laboratory may require a specific type of bottle in which to collect a sample or may provide instructions for chilling a sample after collection. Laboratories establishing sample collection and handling procedures should adhere to protocols defined by the chosen analytical method but may also consult the USGS guidelines for design and sampling for cyanobacterial toxin and taste-and-odor studies in lakes and reservoirs.[26]

EPA has produced technical materials to aid in the development of cyanobacteria and cyanotoxin monitoring programs, including information on available testing methods and sampling logistics.

- For recommendations related to establishing a sampling and monitoring program, see: https://www.epa.gov/cyanohabs/recommendations-cyanobacteria-and-cyanotoxin-monitoring-recreational-waters;
- For a summary of methods used to detect cyanobacteria and cyanotoxins in water, see: Determination of Cyanotoxins in Drinking and Ambient Freshwaters; and,
- For a set of frequently asked questions related to laboratory analysis for microcystins in drinking water, see: Frequently Asked Questions: Laboratory Analysis for Microcystins in Drinking Water.

11. What data and information should states and authorized tribes assemble and evaluate to complete CWA water quality assessments with EPA's recommended cyanotoxin criteria?

States and authorized tribes are required under 40 CFR 130.7(b)(5) to assemble and evaluate all existing and readily available water quality-related data and information when determining which waterbodies belong on the state's or authorized tribe's CWA Section 303(d) list of impaired and threatened waters. "Readily available data and information" relevant to assessment against the recommended recreational criteria for microcystins or cylindrospermopsin would include observed concentration levels for

[24] For more information on how to create a Quality Assurance Project Plan, see https://www.epa.gov/quality/guidance-quality-assurance-project-plans-epa-qag-5.

[25] The National Aquatic Resource Surveys (NARS) collaborative programs between EPA, states, and tribes designed to assess the quality of the nation's waters include field and laboratory procedures for collecting algal toxin samples in the program QAPP, field operation manual and lab operation manual. Additionally, for examples of a state SOPs for collecting and analyzing algal toxin samples, see (1) https://www.kdheks.gov/algae-illness/Response_Plan/Appendix_J.pdf and (2) https://www.dec.ny.gov/docs/water_pdf/habsprogramguide.pdf.

[26] Graham, J.L., Loftin, K.A., Ziegler, A.C., and Meyer, M.T., 2008, Guidelines for design and sampling for cyanobacterial toxin and taste-and-odor studies in lakes and reservoirs: U.S. Geological Survey Scientific Investigations Report 2008–5038. Reston, VA. https://pubs.usgs.gov/sir/2008/5038/.

microcystins and cylindrospermopsin collected by the state, authorized tribe, or other stakeholders (e.g., local health departments, federal agencies, or citizen science water monitoring groups).

EPA also considers swimming advisories to be existing and readily available data and information for completing water quality assessments. Hence, for states and authorized tribes that implement the recommended swimming advisory levels—regardless of whether or not they adopted the recommended criteria—advisories would support water quality assessments using other applicable WQS (e.g., designated uses and narrative criteria).

12. Should states and authorized tribes update their assessment methodology to include the evaluation of cyanotoxin data and information? If so, what should be considered in these updates?

States and authorized tribes should consider updating their water quality assessment methodology, if needed, to address any water quality standard adopted by the state or authorized tribe. An assessment methodology constitutes the decision process that a state or authorized tribe employs to determine the water quality standards attainment status of waters on the state or on tribal lands. Under 40 CFR 130.7(b)(6), states and authorized tribes are required to provide documentation to EPA to support their determination whether to include or not include waters on their impaired and threatened waters lists. States and authorized tribes are required to include a description of the methodology used to develop the list; a description of the data and information used to identify waters for the list, including a description of the data and information used by the jurisdiction; and a rationale for any decisions to not use existing and readily available data and information to develop the list. When updating their methodologies, states and authorized tribes should describe any expectations regarding data and information associated with their cyanotoxin criteria, including any data quality, quantity and representativeness considerations needed to evaluate the recurrence frequency aspect of the criteria. In addition, states and authorized tribes should update their methodologies to describe how they will identify the pollutants (e.g., nutrients) causing or expected to cause violations of the cyanotoxin criteria, consistent with 40 CFR 130.7(b)(4).

EPA encourages states and authorized tribes to make the assessment methodology available to the public for review and comment. Such engagement helps facilitate stakeholder input to the state's or authorized tribe's assessment of water quality status, including recreational use assessments. If states and authorized tribes choose to adopt the recommended cyanotoxin recreational criteria, EPA recommends that they update their assessment methodologies to account for any criteria-specific considerations. For states and authorized tribes that use the swimming advisory recommendation to inform attainment with a narrative water quality standard, EPA also recommends that they describe in their assessment methodology how the advisory information will be evaluated and used to determine attainment of applicable narrative water quality criteria and associated uses.

13. What happens if a state or authorized tribe does not have sufficient data to make an assessment determination?

EPA regulations require that states and authorized tribes assemble and evaluate all existing and readily available water quality-related data and information to develop their CWA Section 303(d) list (40 CFR 130.7(b)(5)). As such, states and authorized tribes must be inclusive in the types of water quality data and information they collect and evaluate. However, EPA recognizes that there may be circumstances when it is not possible to make an attainment decision because the state or authorized tribe has determined that the readily available data and information are insufficient. With regard to EPA's 304(a) recommendation, examples of these circumstances may include, but are not limited to, determining that the cyanotoxin data and information were collected using insufficient QA/QC measures or are not representative of the conditions of the waterbody.

If a state or authorized tribe decides not to rely on certain available information and data in making listing decisions, it must provide a technical, science-based rationale. 40 CFR 130.7(b)(6)(iii). Waters identified as impaired and listed on the Section 303(d) list in the previous reporting cycle should not be removed in the subsequent listing cycle unless the state or authorized tribe can provide a rationale for doing so.

14. What factors should be considered in defining waterbody segmentation (e.g., if dividing a waterbody into smaller assessment units for advisories and CWA Section 303(d) listings)?

States and authorized tribes have flexibility to define the segmentation of waterbodies within their jurisdiction; there is no single approach to the development of a segmentation scheme. Assessment decisions can reflect the broader ecological system (e.g. an entire lake) or be partitioned to smaller components (e.g. smaller assessment units). Whatever approach a state or authorized tribe selects, waterbody segmentation should be consistent with water quality standards and capable of providing a spatial scale that is adequate to characterize attainment status. States and authorized tribes generally segment waters to represent homogeneity in physical, biological or chemical conditions.

15. How should states and authorized tribes approach waterbody assessments for a waterbody that is already on the CWA Section 303(d) list?

Consistent with any applicable water quality standard, states and authorized tribes make future assessment decisions based on an evaluation of existing and readily available water quality-related data and information against the water quality standard using the accompanying assessment method. The assessment decision informs whether a waterbody should be identified as impaired or threatened for microcystins or cylindrospermopsin on the jurisdiction's CWA Section 303(d) list. Waterbodies can be listed as impaired for multiple waterbody/pollutant combinations. When data and information indicate non-attainment for a waterbody that is already on the CWA Section 303(d) list (e.g., waterbodies having impaired recreation use due to *E. coli*, Enterococci or another pollutant), the state or authorized tribe should add microcystins and cylindrospermopsin to the list of impairments for the waterbody already listed as impaired.

For cyanotoxins, states and authorized tribes can decide not to include a waterbody/pollutant combination that was previously identified as impaired or threatened on a state's or tribe's 303(d) list (also known as "delist") for several reasons, including: (a) the water quality standard is now being met, (b) there were flaws in the original listing, (c) a TMDL was developed and approved by EPA, or (d) other point sources or nonpoint source controls are expected to meet WQS as described in 40 CFR 130.7(b)(1). Note that for microcystins and cylindrospermopsin, the number of years of data that would be needed to demonstrate that the water quality criteria are being met would tie back to the recurrence frequency that a state or tribe would have established in its WQS. In addition, for these cyanotoxins, states and authorized tribes could use swimming advisories to inform listing and delisting waters from their CWA Section 303(d) lists based on narrative criteria, as mentioned in Question 12.

Implementation Questions about Water Quality Management Plans (e.g., TMDLs and NPDES permitting)

16. Why should I consider nutrient pollution if I am implementing the recommended criteria for cyanotoxins?

Loading of excess nutrients, including nitrogen and phosphorus, into recreational waterbodies from urban, industrial, and agricultural sources can contribute to cyanobacterial blooms and cyanotoxin production, as nitrogen and phosphorus are required for cyanobacterial growth. Reducing excess nitrogen and phosphorus in a waterbody can help to reduce the occurrence of cyanobacterial blooms or the levels of cyanotoxins in blooms containing toxin-producing strains of cyanobacteria.[27]

The relationships between nutrients and other physical, chemical, or environmental conditions are complex and can present added challenges to recreational waterbody managers responsible for monitoring and responding to cyanobacterial blooms. In addition to nitrogen and phosphorus concentrations, factors such as the availability of organic matter, turbidity, turbulence or flushing of a waterbody, light attenuation, temperature, and pH can play a role in the composition and cyanotoxin production associated with a cyanobacterial bloom. For more information on the factors influencing the occurrence of cyanobacterial blooms and toxin production, see Section 3.1.1 of the recommended criteria document.

The sources of nutrients present in waterbodies are both natural and anthropogenic. Soil and erosion of phosphorus-containing rocks are the most significant natural sources of the phosphorus in surface waters, while resuspension of bed sediment can be the major source of phosphorus to the lower water column. Significant natural sources of nitrogen include fixation of nitrogen gas, N_2, by diazotrophic organisms, as well as dry and wet deposition of naturally derived nitrogen compounds from the atmosphere. Human-caused nutrient pollution comes from several sources, for example:

1. Stormwater runoff in rural and urban areas contains nitrogen and phosphorus from fertilizers (especially those applied in excess or before a rainstorm), yard clippings, leaves, and pet wastes that are washed away to local waterbodies or conveyed through storm sewer systems. Land-based disturbances neighboring a waterbody (such as deforestation, soil compaction, reduced riparian buffers, erosion, or added impermeable surfaces) can increase stormwater runoff and can result in more nutrient pollution and sedimentation.
2. Discharges from municipal wastewater systems contain nitrogen and phosphorus from human waste, food, and certain soaps and detergents.
3. Discharges from industrial facilities, such as fertilizer manufacturers or food processing facilities, are sources of nitrogen and phosphorus.
4. Nonpoint source runoff from agriculture practices, such as the application of fertilizer to row crops and manure management can also be a source of nutrients.

Controlling excess phosphorus and nitrogen inputs could reduce the biomass of cyanobacteria in the system, and the frequency and concentration of microcystins and cylindrospermopsin produced. For

[27] For the results of a study on how the experimental limitation of nutrient supplies aided in the diminishing of a cyanobacterial bloom, see: Pace, M. et al. Reversal of a cyanobacterial bloom in response to early warnings. *Proceedings of the National Academy of Science. USA* 114, 352–357; DOI:10.1073/pnas.1612424114 (2017).

more information on the impact of stressors, including elevated concentrations of total and dissolved phosphorus and nitrogen (e.g., soluble phosphates and nitrates), on the increased production of microcystins and cylindrospermopsin, see Section 3.0 of the national CWA Section 304(a) recommended criteria document.

As a long-term strategy to address eutrophication and cyanobacteria blooms, EPA recommends that states and authorized tribes consider adopting numeric nutrient criteria into their WQS or, alternatively, develop a numeric target to implement a narrative nutrient criterion that has already been adopted into their WQS. Numeric nutrient criteria or targets are useful tools to support water quality assessments, watershed protection or restoration, TMDL development, and permitting programs, where applicable. For information on translating between microcystins and nutrient loads in lakes, see Question 17 and Question 18. EPA stands ready to provide technical assistance to states and authorized tribes who are developing numeric nutrient criteria or targets for different waterbody types through EPA's Nutrient Scientific Technical Exchange Partnership and Support (N-STEPS) program.[28]

EPA continues to provide scientific and technical assistance to states and authorized tribes who are working to reduce excess nutrients as a means of reducing the occurrence of cyanobacterial blooms. For more information on what EPA is doing to help reduce excess nutrients and for tools to assist states and authorized tribes, refer to:

- Preventing Eutrophication: Scientific Support for Dual Nutrient Criteria Factsheet (PDF)
- Managing Microcystin: Identifying National-Scale Thresholds for Total Nitrogen and Chlorophyll a
- Deriving Nutrient Targets to Prevent Excessive Cyanobacterial Densities in U.S. Lakes and Reservoirs (PDF)
- Renewed Call to Action to Reduce Nutrient Pollution and Support for Incremental Actions to Protect Water Quality and Public Health (September 2016 EPA Memo) (PDF)
- Nutrient Pollution Policy and Data
- Toolkit of Resources to Assist States with Adopting and Implementing Numeric Nutrient Criteria
- Water Quality Standards Handbook
- A Compilation of Cost Data Associated with the Impacts and Control of Nutrient Pollution (PDF)

In addition to the EPA resources listed above, the document, World Health Organization: Guidelines for Safe Recreational Water Environments (PDF), contains a chapter on algae and cyanobacteria in freshwater, which includes short- and long-term management options—including nutrient management and implementation of control and abatement technologies, among other practices—with the goal of preventing or reducing the occurrence of cyanobacterial blooms in recreational waters.

17. How should states and authorized tribes complete TMDLs for waterbodies that are listed under CWA Section 303(d) as impaired or threatened due to cyanotoxins?

To address an impairment due to microcystins or cylindrospermopsin, states and authorized tribes would develop TMDLs for the pollutant(s) that promote development of cyanobacterial blooms capable of producing microcystins and cylindrospermopsin at levels above EPA's recommended criteria. As

[28] https://www.epa.gov/nutrient-policy-data/n-steps

previously discussed in this document, excess nutrients (nitrogen and/or phosphorus) and other factors (e.g., temperature) can provide optimal conditions for the formation of cyanobacterial blooms and cyanotoxin production. Accurately deriving the quantity, timing, and geographic distribution of pollutant reductions necessary to meet WQS for cyanotoxins (or cyanobacteria) is a complex process; however, states and authorized tribes can use technical tools to better understand the relationship between the pollutants and the biological and chemical responses associated with cyanobacterial blooms and the production of cyanotoxins such as microcystins. Technical tools that improve the understanding between nutrient pollution and adverse water quality effects associated with both non-toxic and toxic harmful algal blooms include empirical models developed for nutrient water quality criteria development,[29] as well as empirical and mechanistic models used for nutrient TMDLs that address impairments related to dissolved oxygen or elevated algal biomass (which can co-occur with toxic harmful algal blooms). States and authorized tribes may also want to conduct site-specific studies to help refine these relationships and should consider the state of the science as they prioritize and schedule TMDLs to address cyanotoxins.

18. Where a state or authorized tribe has adopted water quality criteria for microcystins and/or cylindrospermopsin, are National Pollutant Discharge Elimination System (NPDES) permits expected to include effluent limits for cyanotoxins?

In general, EPA does not anticipate NPDES permit limits for microcystins or cylindrospermopsin because most facilities subject to NPDES permit requirements do not typically discharge cyanotoxins directly. However, as previously discussed in this document, excess nitrogen and phosphorus loadings can provide optimal conditions for the formation of cyanobacterial blooms and cyanotoxin production. To better inform decisions around how best to control cyanotoxins and meet water quality standards, it may be helpful for NPDES permitting authorities to consider the risk of elevated levels of cyanotoxins in the receiving water when evaluating nutrient requirements in NPDES permits. States and authorized tribes can use technical tools to better understand the relationship between the pollutants—nitrogen and phosphorus—and the biological and chemical responses associated with toxic harmful algal blooms, including cyanotoxins. Technical tools that improve the understanding between nutrient pollution and adverse water quality effects associated with algal blooms, both non-toxic and toxic harmful algal blooms, include empirical models developed for nutrient water quality criteria development,[30] nutrient models

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[29] For example: *Ambient Water Quality Criteria to Address Nutrient Pollution in Lakes and Reservoirs* (EPA-822-R-21-005), U.S. EPA, Office of Water, published July 2021.

[30] For example:

1. Lester L. Yuan and Amina I. Pollard, Managing microcystin: identifying national-scale thresholds for total nitrogen and chlorophyll-a, Freshwater Biology, 59, 9, (1970-1981), (2014).
2. Lester L. Yuan and Amina I. Pollard, Deriving nutrient targets to prevent excessive cyanobacterial densities in U.S. lakes and reservoirs, Freshwater Biology, 60, 9, (1901-1916), (2015).
3. Lester L. Yuan and Amina I. Pollard, Using national-scale data to develop nutrient–microcystin relationships that guide management decisions, Environmental Science & Technology, 51, 12, (6972-6980), (2017).
4. Lester L. Yuan and Amina I. Pollard, Combining national and state data improves predictions of microcystin concentration, Harmful Algae, 84, (75-83), (2019).
5. Lester L. Yuan and John R. Jones, Rethinking phosphorus–chlorophyll relationships in lakes, Limnology and Oceanography, 65, (1847-1857), (2020).

that target dissolved oxygen or elevated algal biomass (which can co-occur with toxic harmful algal blooms), and state and federal technical guidance specific to the development of NPDES permit requirements. The document, *Ambient Water Quality Criteria to Address Nutrient Pollution in Lakes and Reservoirs,* summarizes the latest scientific information on nutrient pollution in lakes and reservoirs.[31] This document was published in July 2021 and contains a valuable summary of the current science on the issue of nutrients and bloom formation.

States and authorized tribes may also want to conduct site-specific studies to help refine these relationships and consider the state of the science as they evaluate the need for nutrient requirements in NPDES permits where there are applicable water quality criteria for cyanotoxins. For waterbodies where TMDLs have been developed to meet applicable water quality criteria for cyanotoxins, and the TMDL includes a waste load allocation for nitrogen and phosphorus, based on translations from microcystin concentrations, the waste load allocation is used to establish permit limits for nitrogen and phosphorus to meet the water quality criteria per 40 CFR 122.44(d)(1)(vii)(B). Conversely, where there are applicable water quality criteria for cyanotoxins but no TMDL for nutrients based on a microcystin translation, NPDES permitting authorities should consider the available science in determining whether nutrient discharges cause, have reasonable potential to cause, or contribute to impairments of applicable water quality criteria for cyanotoxins. Where the Director of the permitting authority determines that nutrient discharges cause, have reasonable potential to cause, or contribute to such impairments, the permit must include nutrient limits that are derived from and comply with the applicable water quality criteria per 40 CFR 122.44(d)(1)(vii)(A).

[31] USEPA. 2021. *Ambient Water Quality Criteria to Address Nutrient Pollution in Lakes and Reservoirs.* EPA-822-R-21-005. U.S. Environmental Protection Agency, Office of Water, Washington, DC. https://www.epa.gov/nutrient-policy-data/epas-recommended-ambient-water-quality-criteria-nutrients.