# The Safe Drinking Water Act & Microcystin

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The federal Safe Drinking Water Act (SDWA), enacted in 1974 and codified as amended at 42 U.S.C. §300j *et seq.*, regulates public water systems. The SDWA requires that the U.S. Environmental Protection Agency (EPA) establish national primary drinking water regulations for contaminants that Congress or EPA has found may have an adverse effect on health if consumed. For each such contaminant, EPA must set a maximum contaminant level (MCL), representing the maximum level allowable for that contaminant in finished drinking water. MCLs are designed to ensure the safety of public drinking water, have the force of law, and are enforceable. Currently, there are no MCLs for microcystin or other cyanotoxins.

Health Advisory (June 2015)

The SDWA authorizes EPA to publish Health Advisories for contaminants that are not currently subject to national primary drinking water regulation. Health Advisories describe non-regulatory concentrations of drinking water contaminants at or below which adverse health effects are not anticipated to occur over specific exposure durations. They serve as informal technical guidance to assist government officials and managers of public water systems. Health Advisories are not legally enforceable and are subject to change.

In June 2015, EPA published a Health Advisory for microcystin in drinking water. The Health Advisory recommended 0.3 micrograms per liter as a level not to be exceeded for pre-school age children, and 1.6 micrograms per liter as a level not to be exceeded for school-age children and adults, based on exposure for 10 days.

Drinking Water Protection Act (August 2015)

Congress in August 2015 enacted the Drinking Water Protection Act, which amends the SDWA. Codified at 42 U.S.C. §300j-19, the legislation directed EPA to develop and submit to Congress, within 90 days, a strategic plan for assessing and managing risks associated with algal toxins in drinking water provided by public water systems. EPA submitted its Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water to Congress in November 2015.

Proposed Unregulated Contaminant Monitoring Rule (December 2015)

The 1996 amendments to the SDWA require that once every five years EPA issue a list of up to 30 unregulated contaminants to be monitored by public water systems. The fourth Unregulated Contaminant Monitoring Rule, as proposed by EPA in December 2015, includes ten cyanotoxin chemical contaminants, including microcystin. 80 Fed. Reg. 76897 (Dec. 11, 2015). If the rule becomes final, all larger public water systems (serving more than 10,000 persons) would be required to monitor for microcystin and certain other cyanotoxins and report their results to EPA.

*This document is a revised and updated version of a handout created by Toledo Law students Arnold Finkbine, Kara Maruszak and Samantha Meiers for Inns of Court in October 2015.*

EPA United States Environmental Protection Agency

Office of Water
820F15003
June 2015

# 2015 Drinking Water Health Advisories for Two Cyanobacterial Toxins

## Summary

EPA has issued 10-Day Drinking Water Health Advisories (HAs) for the cyanobacterial toxins microcystins and cylindrospermopsin.

EPA recommends HA levels at or below 0.3 micrograms per liter for microcystins and 0.7 micrograms per liter for cylindrospermopsin in drinking water for children pre-school age and younger (less than six years old). For school-age children through adults, the recommended HA levels for drinking water are at or below 1.6 micrograms per liter for microcystins and 3.0 micrograms per liter for cylindrospermopsin. Young children are more susceptible than older children and adults as they consume more water relative to their body weight.

HAs are non-regulatory values that serve as informal technical guidance to assist federal, state and local officials, and managers of public or community water systems to protect public health from contaminants. EPA has also published health effects support documents for the cyanobacterial toxins microcystins and cylindrospermopsin. These documents contain the health effects basis for the development of HAs for the protection of human health. In addition, EPA has published a health effects support document for anatoxin-a but concluded that there was not adequate information to support a health advisory for this toxin.

## Background

### *What are cyanobacterial toxins?*

Cyanobacteria, common to freshwater and marine ecosystems, can under certain conditions (high nutrient concentrations and high light intensity) form scums or "blooms" at the surface of a water body. These blooms can produce toxic compounds (cyanobacterial toxins or "cyanotoxins") that are harmful to the environment, animals and human health. Winds and water currents can transport cyanobacterial blooms within proximity to drinking water intakes at treatment plants that, if not removed during treatment, can cause odor, taste and color problems in treated drinking water and can be harmful to human health.

### *What is a health advisory?*

The Safe Drinking Water Act provides the authority for EPA to publish health advisories for contaminants not subject to any national primary drinking water regulation. Health advisories describe non-regulatory concentrations of drinking water contaminants at or below which adverse health effects are not anticipated to occur over specific exposure durations (e.g., one-day, 10-days, several years, and a lifetime). They serve as informal technical guidance to assist federal, state and local officials, and managers of public or community water systems by providing information on the health effects of and methods to sample and treat cyanobacterial toxins in drinking water. HAs are not legally enforceable federal standards and are subject to change as new information becomes available.

### *Why has EPA taken this action?*

There are no U.S. federal guidelines, water quality criteria, standards or regulations for cyanobacteria or cyanotoxins in drinking water under the Safe Drinking Water Act or in surface waters under the Clean Water Act. However, EPA has listed cyanotoxins including microcystin-LR, cylindrospermopsin, and anatoxin–a on the previous and current Contaminant Candidate Lists (CCL), which identify contaminants that may need regulation under the Safe Drinking Water Act.

EPA found there are adequate health effects data to develop HAs for microcystins and cylindrospermopsin, but found the data inadequate to develop an HA for the cyanobacterial toxin anatoxin-a.

### *How Can I Be Exposed to Cyanobacterial Toxins?*

For the cyanotoxin HAs, drinking water is the primary source of exposure. Exposure may also occur by ingestion of toxin contaminated food, including consumption of fish; by inhalation and dermal contact during bathing or showering; and during recreational activities. Effects due to these other routes of exposure cannot be quantified at this time, however, they are assumed to be less than from drinking water ingestion.

## What information was used to develop the health advisories for cyanobacterial toxins?

EPA worked with Health Canada and conducted a comprehensive search of the literature from January 2013 to May 2014. The HA includes information on occurrence; environmental fate; mechanisms of toxicity; acute, short term, subchronic and chronic toxicity and cancer in humans and animals; toxicokinetics; health effects and exposure. The HA also includes information on methods for analysis and treatment techniques for removal in drinking water treatment plants.

### *Health Effects Information*

Effects including gastroenteritis, and liver and kidney damage have been reported in humans following short-term exposure to cyanotoxins in drinking water. Recreational exposure to cyanobacterial blooms has been reported to lead to allergic reactions, including hay fever-like symptoms; skin rashes; and gastrointestinal distress. Animal studies have shown that long-term adverse effects from cyanotoxins include liver and kidney damage. However, more research is needed to quantify these effects.

### *Critical Studies Used*

The critical study supporting the microcystins 10-day HA was conducted by Heinze (1999). This study is a 28-day study in rats, whose drinking water contained microcystin-LR. Effects observed included changes in liver weight, liver serum enzymes, and lesions in the liver. The lowest observed adverse effect level (LOAEL) based on these effects was 50 micrograms per kilogram per day, a no observed adverse effect level (NOAEL) was not identified. This dose was selected as the basis for deriving a reference dose (RfD) for microcystins. A total uncertainty factor of 1000 (10 to account for differences between humans and animals, 10 to account for variability in humans, 3 for extrapolation from a LOAEL, and 3 to address database deficiencies) was applied to determine the RfD for microcystins. These values were used along with body weight and drinking water intake for infants and adults to derive the 10-Day HA values. The 10-day HA of 0.3 µg/L is considered protective of non-carcinogenic adverse health effects for bottle-fed infants and young children of pre-school age over a ten-day exposure to microcystins in drinking water. The 10-day HA of 1.6 µg/L is considered protective of non-carcinogenic adverse health effects for children of school age through adults over a 10-day exposure to microcystins in drinking water.

The critical study supporting the cylindrospermopsin 10-day advisory was conducted by Humpage and Falconer (2002, 2003). This study is an 11-week study with cylindrospermopsin administered to male mice by gavage. Effects observed included increases in kidney weight. The NOAEL from this study was 30 micrograms per kilogram per day and the LOAEL based on kidney weight changes was 60 micrograms per kilogram per day. The NOAEL of 30 micrograms per kilogram per day was selected as the basis for the RfD. A total uncertainty factor of 300 (10 to account for differences between humans and animals, 10 to account for variability in humans, and 3 to address database deficiencies) was applied to determine the RfD for cylindrospermopsin. These values were used along with body weight and drinking water intake for infants and adults to derive the 10-Day HA values. The 10-day HA of 0.7 µg/L is considered protective of non-carcinogenic adverse health effects for bottle-fed infants and young children of pre-school age over a 10-day exposure to cylindrospermopsin in drinking water. The 10-day HA of 3 µg/L is considered protective of non-carcinogenic adverse health effects for children of

school age through adults over a 10-day exposure to cylindrospermopsin in drinking water.

As the science on the health impacts of algal toxins continues to improve, EPA will track developments and update recommendations as appropriate.

## Additional EPA support document to assist states and utilities in managing cyanobacterial toxins

EPA has also published a cyanotoxin management document as a companion to the HAs. The document is designed to provide information and a framework that Public Water Systems and others can consider to inform their decisions on managing the risks from cyanotoxins to drinking water. It includes a potential stepwise approach these systems could use to inform their decisions on whether and how to monitor and treat water, and communicate with stakeholders.

## Where can I find more information?

To learn more about the HAs for microcystins and cylindrospermopsin and to view the health effects support documents for these and anatoxin-a in drinking water, visit EPA's Health Advisory webpage: http://water.epa.gov/drink/standards/hascience.cfm. To learn about additional strategies Public Water Systems and others could consider in managing cyanotoxins, visit EPA's CyanoHABs website: http://www2.epa.gov/nutrient-policy-data/guidelines-and-recommendations

### *References*


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# Drinking Water Health Advisory for the Cyanobacterial Microcystin Toxins

Prepared by:

U.S. Environmental Protection Agency
Office of Water (4304T)
Health and Ecological Criteria Division
Washington, DC 20460

EPA Document Number: 820R15100
Date: June 15, 2015

## EXECUTIVE SUMMARY

Microcystins are toxins produced by a number of cyanobacteria species, including members of *Microcystis*, *Anabaena*, *Nodularia*, *Nostoc, Oscillatoria*, *Fischerella*, *Planktothrix*, and *Gloeotrichia*. Approximately 100 microcystin congeners exist, which vary based on amino acid composition. Microcystin-LR is one of the most potent congeners and the majority of toxicological data on the effects of microcystins are available for this congener.

Many environmental factors such as the ratio of nitrogen to phosphorus, temperature, organic matter availability, light attenuation and pH play an important role in the development of microcystin blooms, both in fresh and marine water systems and could encourage toxin production. Microcystins are water soluble and tend to remain contained within the cyanobacterial cell (intracellular), until the cell breaks and they are released into the water (extracellular).

This Health Advisory (HA) for microcystins is focused on drinking water as the primary source of exposure. Exposure to cyanobacteria and their toxins may also occur by ingestion of toxin-contaminated food, including consumption of fish, and by inhalation and dermal contact during bathing or showering and during recreational activities in waterbodies with the toxins. While these types of exposures cannot be quantified at this time, they are assumed to contribute less to the total cyanotoxin exposures than ingestion of drinking water. Due to the seasonality of cyanobacterial blooms, exposures are not expected to be chronic.

Limited data in humans and animals demonstrate the absorption of microcystins from the intestinal tract and distribution to the liver, brain, and other tissues. Elimination from the body requires facilitated transport using receptors belonging to the Organic Acid Transporter polypeptide (OATp) family. Data for humans and other mammals suggest that the liver is a primary site for binding these proteins (i.e., increased liver weight in laboratory animals and increased serum enzymes in laboratory animals and humans). Once inside the cell, these toxins covalently bind to cytosolic proteins (PP1 and PP2) resulting in their retention in the liver. Limited data are available on the metabolism of microcystins, but most of the studies indicate that microcystins can be conjugated with glutathione and cysteine to increase their solubility and facilitate excretion.

The main source of human health effects data for microcystins is from acute recreational exposure to cyanobacterial blooms. Symptoms include headache, sore throat, vomiting and nausea, stomach pain, dry cough, diarrhea, blistering around the mouth, and pneumonia. However, human data on the oral toxicity of microcystins are limited and confounded by: potential co-exposure to other contaminants; a lack of quantitative information; and other confounding factors. Reports of human intravenous exposure to dialysate prepared with microcystin-contaminated water indicated acute liver failure and death in a large number of the exposed patients.

Studies in laboratory animals demonstrate liver, kidney, and reproductive effects following short-term and subchronic oral exposures to microcystin-LR. Studies evaluating the chronic toxicity of microcystins have not shown clinical signs of toxicity and are limited by study design and by the lack of quantitative data.

The U.S. Environmental Protection Agency (EPA) identified a study by Heinze (1999) conducted on rats as the critical study used in the derivation of the reference dose (RfD) for microcystins. The critical effects identified in the study are increased liver weight, slight to moderate liver lesions with hemorrhages, and increased enzyme levels as a result of exposure to microcystin-LR. The lowest-observed-adverse-effect level (LOAEL) was determined to be 50 μg/kg/day, based on these effects. The drinking water route of exposure matches potential drinking water exposure scenarios in humans. The total uncertainty factor (UF) applied to the LOAEL was 1000. This was based on a UF of 10 for intraspecies variability, a UF of 10 for interspecies variability, a UF of 3 ($10^{½}$) for extrapolation from a LOAEL to no-observed-adverse-effect level (NOAEL), and a UF of 3 ($10^{½}$) to account for deficiencies in the database. EPA is using microcystin-LR as a surrogate for other microcystin congeners. Therefore, the HA based on this critical study applies to total microcystins.

EPA is issuing a Ten-day HA for microcystins based on the Heinze (1999) short-term, 28-day study. Studies of a duration of 7 to 30 days are typically used to derive Ten-day HAs. The HA is consistent with this duration and appropriately matches human exposure scenarios for microcystins in drinking water. Cyanobacterial blooms are usually seasonal, typically occurring from May through October. Microcystins typically have a half-life of 4 days to 14 days in surface waters, (depending on the degree of sunlight, natural organic matter, and the presence of bacteria) and can be diluted via transport. In addition, concentrations in finished drinking water can be reduced by drinking water treatment and management measures.

The Ten-day HA value for bottle-fed infants and young children of pre-school age is 0.3 μg/L and for school-age children through adults is 1.6 μg/L for microcystins. The two advisory values use the same toxicity data (RfD) and represent differences in drinking water intake and body weight for different life stages. The first advisory value is based on the summation of the time-weighted drinking water intake/body weight ratios for birth to <12 months of age. The second advisory value is based on the mean body weight and 90$^{th}$ percentile drinking water consumption rates for adults age 21 and over (U.S. EPA's Exposure Factors Handbook (2011a)), which is similar to that of school-aged children. Populations such as pregnant women and nursing mothers, the elderly, and immune-compromised individuals or those receiving dialysis treatment may be more susceptible than the general population to the health effects of microcystins. As a precautionary measure, individuals that fall into these susceptible groups may want to consider following the recommendations for children pre-school age and younger. This HA is not a regulation, it is not legally enforceable, and it does not confer legal rights or impose legal obligations on any party.

Applying the U.S. EPA (2005) Guidelines for Carcinogen Risk Assessment, there is *inadequate information to assess carcinogenic potential* of microcystins. The few available epidemiological studies are limited by their study design, poor measures of exposure, potential co-exposure to other contaminants, and the lack of control for confounding factors. No long term animal studies were available to evaluate dose-response for the tumorigenicity of microcystins following lifetime exposures. Other studies evaluating the tumor promotion potential of microcystin found an increase in the number and/or size of GST-P positive foci observed. In two promotion studies, microcystin-LR alone showed no initiating activity.

# Public Law 114–45
# 114th Congress

## An Act

To amend the Safe Drinking Water Act to provide for the assessment and management of the risk of algal toxins in drinking water, and for other purposes.

Aug. 7, 2015
[H.R. 212]

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

Drinking Water Protection Act.
42 USC 201 note.

This Act may be cited as the "Drinking Water Protection Act".

**SEC. 2. AMENDMENT TO THE SAFE DRINKING WATER ACT.**

(a) AMENDMENT.—Part E of the Safe Drinking Water Act (42 U.S.C. 300j et seq.) is amended by adding at the end the following new section:

**"SEC. 1459. ALGAL TOXIN RISK ASSESSMENT AND MANAGEMENT.**

42 USC 300j–19.

"(a) STRATEGIC PLAN.—

"(1) DEVELOPMENT.—Not later than 90 days after the date of enactment of this section, the Administrator shall develop and submit to Congress a strategic plan for assessing and managing risks associated with algal toxins in drinking water provided by public water systems. The strategic plan shall include steps and timelines to—

Deadline.
Health and health care.

"(A) evaluate the risk to human health from drinking water provided by public water systems contaminated with algal toxins;

"(B) establish, publish, and update a comprehensive list of algal toxins which the Administrator determines may have an adverse effect on human health when present in drinking water provided by public water systems, taking into account likely exposure levels;

"(C) summarize—

"(i) the known adverse human health effects of algal toxins included on the list published under subparagraph (B) when present in drinking water provided by public water systems; and

"(ii) factors that cause toxin-producing cyanobacteria and algae to proliferate and express toxins;

"(D) with respect to algal toxins included on the list published under subparagraph (B), determine whether to—

"(i) publish health advisories pursuant to section 1412(b)(1)(F) for such algal toxins in drinking water provided by public water systems;

"(ii) establish guidance regarding feasible analytical methods to quantify the presence of algal toxins; and

"(iii) establish guidance regarding the frequency of monitoring necessary to determine if such algal toxins are present in drinking water provided by public water systems;

"(E) recommend feasible treatment options, including procedures, equipment, and source water protection practices, to mitigate any adverse public health effects of algal toxins included on the list published under subparagraph (B); and

"(F) enter into cooperative agreements with, and provide technical assistance to, affected States and public water systems, as identified by the Administrator, for the purpose of managing risks associated with algal toxins included on the list published under subparagraph (B).

"(2) UPDATES.—The Administrator shall, as appropriate, update and submit to Congress the strategic plan developed under paragraph (1).

Health and health care.

"(b) INFORMATION COORDINATION.—In carrying out this section the Administrator shall—

"(1) identify gaps in the Agency's understanding of algal toxins, including—

"(A) the human health effects of algal toxins included on the list published under subsection (a)(1)(B); and

"(B) methods and means of testing and monitoring for the presence of harmful algal toxins in source water of, or drinking water provided by, public water systems;

"(2) as appropriate, consult with—

"(A) other Federal agencies that—

"(i) examine or analyze cyanobacteria or algal toxins; or

"(ii) address public health concerns related to harmful algal blooms;

"(B) States;

"(C) operators of public water systems;

"(D) multinational agencies;

"(E) foreign governments;

"(F) research and academic institutions; and

"(G) companies that provide relevant drinking water treatment options; and

"(3) assemble and publish information from each Federal agency that has—

"(A) examined or analyzed cyanobacteria or algal toxins; or

"(B) addressed public health concerns related to harmful algal blooms.

"(c) USE OF SCIENCE.—The Administrator shall carry out this section in accordance with the requirements described in section 1412(b)(3)(A), as applicable.

"(d) FEASIBLE.—For purposes of this section, the term 'feasible' has the meaning given such term in section 1412(b)(4)(D).".

(b) REPORT TO CONGRESS.—Not later than 90 days after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report that includes—

(1) an inventory of funds—

(A) expended by the United States, for each of fiscal years 2010 through 2014, to examine or analyze toxin-producing cyanobacteria and algae or address public health concerns related to harmful algal blooms; and

(B) that includes the specific purpose for which the funds were made available, the law under which the funds were authorized, and the Federal agency that received or spent the funds; and

(2) recommended steps to reduce any duplication, and improve interagency coordination, of such expenditures.

Approved August 7, 2015.

LEGISLATIVE HISTORY—H.R. 212:

HOUSE REPORTS: No. 114–26 (Comm. on Energy and Commerce).
CONGRESSIONAL RECORD, Vol. 161 (2015):
Feb. 24, considered and passed House.
Aug. 5, considered and passed Senate.

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United States
Environmental Protection
Agency

# Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water

Strategy Submitted to Congress to Meet the Requirements of P.L. 114-45

Product of the
United States Environmental Protection Agency

**810R04003**

November 2015

# *Table of Contents*

## *I. Executive Summary*

The prevalence and duration of harmful algal blooms (HABs) in freshwater is rapidly expanding in the United States and worldwide. The water quality, human health and socioeconomic impacts of HABs can be significant. Some HABs can produce toxins that are toxic to liver, kidney and nervous system functions in humans and animals. These toxins, when found in source waters, can contaminate drinking water supplies if that water is not adequately treated. The challenges that HABs pose to public drinking water systems include an incomplete understanding of how to prevent, predict, analyze, monitor and treat toxins in drinking water; determining how to effectively communicate risk to stakeholders; and developing and implementing resource-efficient methods to reduce the risks posed by HABs in source waters.

The United States Environmental Protection Agency (EPA) developed this document in accordance with Section 1459 of the Safe Drinking Water Act, as amended by the Drinking Water Protection Act, which requires that the Administrator of the EPA develop a strategic plan for assessing and managing risks associated with algal toxins in drinking water provided by public water systems. This plan presents examples of recently completed and ongoing HAB-related activities and provides steps and timelines for intended future EPA activities. These ongoing and future activities outline EPA's plan for the next few months through the next five years and beyond. This plan addresses:

**Algal Toxins and Their Human Health Effects**
*Evaluating the risk to human health from drinking water contaminated with algal toxins provided by public water systems; establishing, publishing and updating a comprehensive list of algal toxins that may have an adverse effect on human health when found in drinking water provided by public water systems; and summarizing those health effects.*
Steps include: 1) Building on the existing work of compiling information on mechanisms of toxicity in human and animals for the toxins microcystins, cylindrospermopsin and anatoxin-*a*; 2) evaluating information gaps and analyzing the human health risk posed by other toxins of human health concern; and 3) determining whether sufficient information is available to develop health advisories for additional toxins.

**Health Advisories**
*Determining whether to publish additional health advisories for the algal toxins represented on the comprehensive list of algal toxins that may have an adverse effect on human health when found in drinking water provided by public water systems.*
Steps include: 1) Determining if adequate occurrence, toxicology and epidemiology data are available to develop health advisories for the listed toxins other than those established in June 2015 for the cyanotoxins microcystins and cylindrospermopsin; 2) evaluating the toxicity of these listed toxins including the toxico-dynamics and toxicokinetics of microcystin congeners; and 3) analyzing the adverse effects to the reproductive system from exposure to microcystins.

**Factors Likely To Cause Harmful Algal Blooms**
*Summarizing the factors that cause toxin-producing cyanobacteria and algae to proliferate and express toxins.*
Steps include: 1) Building on research to better understand HAB ecology; 2) developing tools to quantify HABs in U.S. freshwater lakes and reservoirs using satellite color data; 3) evaluating, interpreting and linking existing data on algal toxins and the factors that impact their occurrence, including nutrient

loading and climate change; and 4) identifying areas where more monitoring is necessary to support scientific understanding.

**Analytical Methods**
*Establishing additional guidance regarding feasible analytical methods to quantify the presence of algal toxins.*
Steps include: 1) Building on efforts to evaluate the comparability of rapid screening methods and more specific analytical methods; 2) evaluating methods to fill knowledge gaps and provide improved analytical methods for algal toxins in drinking water; and 3) providing standardized and validated detection and analysis methods, as needed, for emerging algal toxins of concern.

**Frequency of Monitoring**
*Evaluating the frequency of monitoring necessary to determine if such algal toxins are present in drinking water provided by public water systems.*
Steps include: 1) Engaging with states and public water systems to update and refine the existing guidance on monitoring frequency as more information becomes available; and 2) using emerging science on factors affecting HABs and algal toxins to inform monitoring frequencies.

**Treatment Options**
*Evaluating feasible treatment options, including procedures and equipment to mitigate any adverse public health effects of algal toxins included on the published algal toxin list.*
Steps include: 1) Summarizing the state of knowledge regarding water treatment optimization and identifying approaches to assist with treatment challenges related to HAB events; 2) researching the removal effectiveness of unit operations for various toxins and developing better predictive tools/models; and 3) investigating how to implement treatment process and operational changes for maximum protection and cost-effectiveness under a variety of site-specific constraints.

**Source Water Protection Practices**
*Evaluating and recommending feasible source water protection practices to mitigate any adverse public health effects of algal toxins included on the published list.*
Steps include: 1) Expanding computerized mapping and water quality modeling for HAB detection and prediction at the watershed scale; 2) monitoring nutrients across watersheds to both target and assess protection activities; 3) working with states to prioritize nutrient-impacted waterbodies for water quality improvements and developing targets for clean-up; and 4) collaboratively working across the EPA's regional offices to promote awareness amongst the public drinking water systems on the monitoring, screening techniques and source water protection practices.

Additionally, this plan outlines a strategy for continuing to utilize cooperative agreements and provide technical assistance to states and public water systems to address HABs.

EPA United States Environmental Protection Agency

## Monitoring Unregulated Drinking Water Contaminants

# Fourth Unregulated Contaminant Monitoring Rule

The 1996 Safe Drinking Water Act (SDWA) amendments require that once every five years EPA issue a new list of no more than 30 unregulated contaminants to be monitored by public water systems (PWSs).

The fourth Unregulated Contaminant Monitoring Rule (UCMR 4) was proposed on December 11, 2015. The proposal outlines monitoring for 30 chemical contaminants between 2018 and 2020 using analytical methods developed by EPA and consensus organizations. This monitoring provides a basis for future regulatory determinations and, as warranted, actions to protect public health.

- Federal Register Notice: Proposal - Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 4) for Public Water Systems and Announcement of a Public Meeting
- Public Stakeholder Meeting (Webinar): January 13, 2016

## Proposed UCMR 4 analytical methods and contaminants

### Assessment Monitoring (List 1 contaminants)

The proposed Assessment Monitoring sampling time frame addresses the period of March 2018 through November 2020. See table below for the proposed sampling design.

**National Sample Assessment Monitoring Design**

| System Size (# of people served) | 10 List 1 Cyanotoxins | 20 Additional List 1 Chemicals |
|---|---|---|
| Small Systems (25 – 10,000) | 800 randomly selected surface water (SW) or ground water under the direct influence of surface water (GWUDI) systems | 800 randomly selected SW, GWUDI and ground water (GW) systems |
| Large Systems (10,001 and over) | All SW or GWUDI systems | All SW, GWUDI and GW systems |

- Total for small systems is additive because these systems would only be selected for one component of UCMR 4 sampling (10 cyanotoxins or 20 additional chemicals). EPA would pay for all analytical costs associated with monitoring at small systems.
- The number of large systems is not additive. All SW and GWUDI systems would monitor for cyanotoxins; those same systems would also monitor for the 20 additional List 1 chemicals, as would the large GW systems.

**Ten Cyanotoxin Chemical Contaminants[3,4]**

| Contaminant | CAS Registry Number[1] | Minimum Reporting Level | Sampling Points[2] | Analytical Methods |
|---|---|---|---|---|
| total microcystin | N/A | 0.3 µg/L | EPTDS and SR | ELISA Exit |
| microcystin-LA | 96180-79-9 | 0.008 µg/L | EPTDS | EPA 544 |
| microcystin-LF | 154037-70-4 | 0.006 µg/L | EPTDS | EPA 544 |
| microcystin-LR | 101043-37-2 | 0.02 µg/L | EPTDS | EPA 544 |
| microcystin-LY | 123304-10-9 | 0.009 µg/L | EPTDS | EPA 544 |
| microcystin-RR | 111755-37-4 | 0.006 µg/L | EPTDS | EPA 544 |
| microcystin-YR | 101064-48-6 | 0.02 µg/L | EPTDS | EPA 544 |
| Nodularin | 118399-22-7 | 0.005 µg/L | EPTDS | EPA 544 |
| anatoxin-a | 64285-06-9 | 0.03 µg/L | EPTDS | EPA 545 |
| cylindrospermopsin | 143545-90-8 | 0.09 µg/L | EPTDS | EPA 545 |

**Two Metals**

(6) Testing, monitoring, reporting and recordkeeping requirements for the designated facilities;

(7) Records of the public hearing on the State SSI plan; and,

(8) Provisions for annual state progress reports to EPA on implementation of the State plan.

The EPA proposes to determine that Puerto Rico's State SSI plan for existing SSI units includes all the required State plan elements described in section 60.5015 of the EG.

*B. What approval criteria did the EPA use to evaluate Puerto Rico's State SSI plan?*

The EPA reviewed Puerto Rico's State SSI plan for approval against the following criteria: 40 CFR 60.23 through 60.26, "Subpart B—Adoption and Submittal of State Plans for Designated Facilities;" and 40 CFR 60.5000 through 60.5250, "Subpart MMMM—Emission Guidelines and Compliance Times for Existing Sewage Sludge Incineration Units;" and 40 CFR 62, subpart A, "General Provisions" for "Approval and Promulgation of State Plans for Designated Facilities and Pollutants."

## IV. What is the EPA's Conclusion?

The EPA has determined that Puerto Rico's State SSI plan meets all the applicable approval criteria as discussed above and, therefore, the EPA is proposing to approve Puerto Rico's sections 111(d) and 129 State plan for existing sewage sludge incineration units. As explained above, at the request of Puerto Rico, the EPA is proposing to not take any action on the affirmative defense provisions in Puerto Rico's State SSI plan.

## V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a 111(d)/129 plan submission that complies with the provisions of the Act and applicable Federal regulations. 40 CFR 62.04. Thus, in reviewing 111(d)/129 plan submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The 111(d)/129 plan is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian Nation Land, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

## List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Aluminum, Fertilizers, Fluoride, Intergovernmental relations, Paper and paper products industry, Phosphate, Reporting and recordkeeping requirements, Sulfur oxides, Sulfur acid plants, waste treatment and disposal.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: November 30, 2015.

**Judith A. Enck,**

*Regional Administrator, Region 2.*

[FR Doc. 2015–31182 Filed 12–10–15; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 141

**[EPA–HQ–OW–2015–0218; FRL–9935–74–OW]**

**RIN 2040–AF10**

## Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 4) for Public Water Systems and Announcement of a Public Meeting

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule and notice of public meeting.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is proposing a Safe Drinking Water Act (SDWA) rule that requires public water systems to collect occurrence data for contaminants that may be present in tap water but are not yet subject to EPA's drinking water standards set under SDWA. This rule, revised every five years as required by SDWA, benefits public health by providing EPA and other interested parties with scientifically valid data on the national occurrence of selected contaminants in drinking water, such as cyanotoxins associated with harmful algal blooms. This data set is one of the primary sources of information on occurrence, levels of exposure and population exposure the Agency uses to develop regulatory decisions for emerging contaminants in the public drinking water supply. This proposal identifies eleven analytical methods to support water system monitoring for a total of 30 chemical contaminants/groups, consisting of ten cyanotoxins/groups; two metals; eight pesticides plus one pesticide manufacturing byproduct (hereinafter collectively referred to as "pesticides"); three brominated haloacetic acid groups of disinfection byproducts; three alcohols; and three semivolatile organic chemicals. EPA is also announcing a public webinar to discuss this proposal of the fourth Unregulated Contaminant Monitoring Rule.

**DATES:** Comments must be received on or before February 9, 2016. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before January 11, 2016. The public webinar will be held on January 13, 2016, from 1:00 p.m.. to 4:30 p.m., eastern time. Persons wishing to participate in the webinar must register

by January 10, 2016, as described in section II.M.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–OW–2015–0218, at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

**FOR FURTHER INFORMATION CONTACT:** Brenda D. Parris, Standards and Risk Management Division (SRMD), Office of Ground Water and Drinking Water (OGWDW) (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH 45268; telephone number: (513) 569–7961; or email address: *parris.brenda@epa.gov;* or Melissa Simic, SRMD, OGWDW (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268; telephone number: (513) 569–7864; or email address: *simic.melissa@epa.gov*. For general information, contact the Safe Drinking Water Hotline. Callers within the United States can reach the Hotline at (800) 426–4791. The Hotline is open Monday through Friday, excluding federal holidays, from 10 a.m. to 4 p.m., eastern time. The Safe Drinking Water Hotline can also be found on the Internet at: *http://water.epa.gov/drink/hotline/*.

**SUPPLEMENTARY INFORMATION:**

## Table of Contents



## Abbreviations and Acronyms

μg/L Microgram per liter
ADDA (*2S, 3S, 8S, 9S, 4E, 6E*)-3-amino-9-methoxy-2,6,8-trimethyl-10-phenyl-4, 6-decadienoic acid
ASDWA Association of State Drinking Water Administrators
ASTM ASTM International
CAS Chemical Abstract Service
CBI Confidential Business Information
CCC Continuing Calibration Check
CCL Contaminant Candidate List
CFR Code of Federal Regulations
CLDA Chlorine Dioxide Applied After SR Sample Location
CLDB Chlorine Dioxide Applied Before SR Sample Location
CWS Community Water System
DBPR Disinfectants and Disinfection Byproducts Rule
DSMRT Distribution System Maximum Residence Time
ELISA Enzyme-linked Immunosorbent Assay
EPA United States Environmental Protection Agency
EPTDS Entry Point to the Distribution System
FR Federal Register
GC Gas Chromatography
GC/ECD Gas Chromatography/Electron Capture Detection
GC/MS Gas Chromatography/Mass Spectrometry
GW Ground Water
GWUDI Ground Water Under the Direct Influence of Surface Water
HAAs Haloacetic Acids
HAA5 Dibromoacetic Acid, Dichloroacetic Acid, Monobromoacetic Acid, Monochloroacetic Acid, Trichloroacetic Acid
HAA6Br Bromochloroacetic Acid, Bromodichloroacetic Acid, Dibromoacetic Acid, Dibromochloroacetic Acid, Monobromoacetic Acid, Tribromoacetic Acid
HAA9 Bromochloroacetic Acid, Bromodichloroacetic Acid, Chlorodibromoacetic Acid, Dibromoacetic Acid, Dichloroacetic Acid, Monobromoacetic Acid, Monochloroacetic Acid, Tribromoacetic Acid, Trichloroacetic Acid
HPXA Hydrogen Peroxide Applied After Source Water Sample Location
HPXB Hydrogen Peroxide Applied Before Source Water Sample Location
IC–MS/MS Ion Chromatography/Tandem Mass Spectrometry
ICP–MS Inductively Coupled Plasma Mass Spectrometry
ICR Information Collection Request
IDC Initial Demonstration of Capability
IS Internal Standard
LFB Laboratory Fortified Blank

LRB Laboratory Reagent Blank
LCMRL Lowest Concentration Minimum Reporting Level
LC/ECI–MS/MS Liquid Chromatography/Electrospray Ionization/Tandem Mass Spectrometry
LC/MS/MS Liquid Chromatography/Tandem Mass Spectrometry
LT2 Long Term 2 Enhanced Surface Water Treatment Rule
M Million
MRL Minimum Reporting Level
NAICS North American Industry Classification System
NCOD National Drinking Water Contaminant Occurrence Database
NPDWRs National Primary Drinking Water Regulations
NTNCWS Non-transient Non-community Water System
OGWDW Office of Ground Water and Drinking Water
OMB Office of Management and Budget
PA Partnership Agreement
PEMA Permanganate Applied After Source Water Sample Location
PEMB Permanganate Applied Before Source Water Sample Location
PRA Paperwork Reduction Act
PT Proficiency Testing
PWS Public Water System
QCS Quality Control Sample
QH Quality HAA Sample
RFA Regulatory Flexibility Act
SDWA Safe Drinking Water Act
SDWARS Safe Drinking Water Accession and Review System
SDWIS/Fed Federal Safe Drinking Water Information System
SM Standard Methods
SMP State Monitoring Plan
SOP Standard Operating Procedure
SPE Solid Phase Extraction
SR Source Water
SRF Drinking Water State Revolving Fund
SRMD Standards and Risk Management Division
SUR Surrogate Standard
SVOCs Semivolatile Organic Chemicals
SW Surface Water
TNCWS Transient Non-Community Water System
TOC Total Organic Carbon
UCMR Unregulated Contaminant Monitoring Rule
UMRA Unfunded Mandates Reform Act of 1995
USEPA United States Environmental Protection Agency

## I. General Information

### *A. Does this action apply to me?*

Public water systems (PWSs) would be regulated by this proposed, fourth Unregulated Contaminant Monitoring Rule (UCMR 4). PWSs are systems that provide water for human consumption through pipes, or other constructed conveyances, to at least 15 service connections or that regularly serve an average of at least 25 individuals daily at least 60 days out of the year. Under this proposal, all large community and non-transient non-community water systems (NTNCWSs) serving more than 10,000 people would be required to monitor. A community water system (CWS) means a PWS that has at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents. A NTNCWS means a PWS that is not a CWS and that regularly serves at least 25 of the same people over six months per year. A nationally representative sample of CWSs and NTNCWSs serving 10,000 or fewer people would also be required to monitor (see "Statistical Design and Sample Selection for the Unregulated Contaminant Monitoring Regulation" (USEPA, 2001b) for a description of the statistical approach for the nationally representative sample). As is generally the case for UCMR monitoring, transient non-community water systems (TNCWSs) (*i.e.,* non-community water systems that do not regularly serve at least 25 of the same people over six months per year) would not be required to monitor under UCMR 4. States, territories and tribes, with primary enforcement responsibility (primacy) to administer the regulatory program for PWSs under SDWA, can participate in the implementation of UCMR 4 through Partnership Agreements (PAs) (see discussion of PAs in section II.K). Primacy agencies with PAs can choose to be involved in various aspects of the UCMR 4 monitoring for PWSs they oversee; however, the PWS remains responsible for compliance. Potentially regulated categories and entities are identified in the following table.

| Category | Examples of potentially regulated entities | NAICS [a] |
|---|---|---|
| State, local, & tribal governments | States, local and tribal governments that analyze water samples on behalf of PWSs required to conduct such analysis; states, local and tribal governments that directly operate CWSs and NTNCWSs required to monitor. | 924110 |
| Industry | Private operators of CWSs and NTNCWSs required to monitor | 221310 |
| Municipalities | Municipal operators of CWSs and NTNCWSs required to monitor | 924110 |

[a] NAICS = North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table summarizes the types of entities that EPA is aware could potentially be regulated by this action. If you are uncertain whether your entity is regulated by this action after carefully examining the definition of PWS found in §§ 141.2 and 141.3, and the applicability criteria found in § 141.40(a)(1) and (2) of Title 40 in the Code of Federal Regulations (CFR), please consult the contacts listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

### *B. What action is the Agency taking and why?*

EPA is proposing a rule to require PWSs to analyze drinking water samples for unregulated contaminants that do not have health based standards set under SDWA and to report their results to EPA. This will be the fourth national monitoring effort under the UCMR program (see section II.D). The monitoring provides data to inform future regulatory actions to protect public health.

The public will benefit from information about whether or not unregulated contaminants are present in their drinking water. If contaminants are not found, consumer confidence in their drinking water will improve. If contaminants are found, illnesses may be avoided when subsequent actions, such as regulations, reduce or eliminate those contaminants.

### *C. What is the Agency's authority for taking this action?*

As part of its responsibilities under SDWA, EPA implements section 1445(a)(2), Monitoring Program for Unregulated Contaminants. This section, as amended in 1996, requires that once every five years, beginning in August 1999, EPA issue a list of no more than 30 unregulated contaminants to be monitored by PWSs. SDWA requires that EPA enter the monitoring data into the Agency's publically available National Contaminant Occurrence Database (NCOD). EPA's UCMR program must ensure that systems serving a population larger than 10,000 people, as well as a nationally representative

sample of PWSs serving 10,000 or fewer people, are required to monitor. EPA must vary the frequency and schedule for monitoring based on the number of persons served, the source of supply and the contaminants likely to be found. EPA is using this authority as the basis for monitoring 29 of the 30 contaminants/groups proposed under this rule.

Section 1445(a)(1)(A) of SDWA, as amended in 1996, requires that every person who is subject to any SDWA requirement establish and maintain such records, make such reports, conduct such monitoring and provide such information as the Administrator may reasonably require by regulation to assist the Administrator in establishing SDWA regulations. Pursuant to this provision, EPA can also require the monitoring of contaminants already subject to EPA's drinking water standards. EPA is using this authority as the basis for monitoring one of the chemical groups (Haloacetic Acids 5 (HAA5)) proposed under this rule. Sample collection and analysis for HAA5 can be done concurrent with the unregulated HAA monitoring described in section II.F (resulting in no substantive additional burden) and would allow EPA to better understand co-occurrence between regulated and unregulated disinfection byproducts.

Hereinafter, all 30 proposed contaminants/groups are collectively referred to as "contaminants."

*D. What is the estimated cost of this proposed action?*

EPA estimates the total average national cost of this proposed action will be $25.3 million per year from 2017–2021. EPA has documented the assumptions and data sources used in the preparation of this estimate in the Information Collection Request (ICR) (USEPA, 2015a). EPA proposes using eleven analytical methods (eight EPA-developed analytical methods, one state-developed methodology and two alternate equivalent consensus organization-developed methods) to analyze samples for 30 UCMR 4 chemical contaminants. EPA's estimate of the analytical cost for the UCMR 4 contaminants and related indicators is $2,562 per sample set. EPA calculated these costs by summing the laboratory unit cost of each method. Exhibit 1 presents a breakdown of EPA estimated annual average national costs. Estimated PWS (*i.e.*, large and very large) and EPA costs reflect the analytical cost (*i.e.*, non-labor) for all UCMR 4 methods. EPA pays for the analytical costs for all systems serving a population of 10,000 or fewer people. Laboratory analysis and sample shipping account for approximately 80% of the total national cost for UCMR 4 implementation. EPA estimated laboratory unit costs based on consultations with multiple commercial drinking water laboratories and, in the case of new methods, a review of the costs of analytical methods similar to those proposed in this action. The cost of the laboratory methods includes shipping as part of the cost for the analysis.

EPA expects that states would incur labor costs associated with voluntary assistance with UCMR 4 implementation. EPA estimated state costs using the relevant assumptions from the State Resource Model that was developed by the Association of State Drinking Water Administrators (ASDWA) (ASDWA, 2013) to help states forecast resource needs. Model estimates were adjusted to account for actual levels of state participation under UCMR 3. State participation is voluntary; thus, the level of effort is expected to vary among states and would depend on their individual agreements with EPA.

EPA assumes that one-third of the systems would monitor during each of the three monitoring years from January 2018 through December 2020. The total estimated annual costs (labor and non-labor) would be incurred as follows:

EXHIBIT 1—ESTIMATED AVERAGE ANNUAL COSTS OF UCMR 4

| Respondent | Avg. annual cost all respondents (2017–2021) [1] |
|---|---|
| Small Systems (25–10,000), including labor [2] only (non-labor costs [3] paid for by EPA) | $0.16 m |
| Large Systems (10,001–100,000), including labor and non-labor costs | $15.7 m |
| Very Large Systems (100,001 and greater), including labor and non-labor costs | $4.3 m |
| States, including labor costs related to implementation coordination | $0.50 m |
| EPA, including labor for implementation, non-labor for small system testing | $4.7 m |
| **AVERAGE ANNUAL NATIONAL TOTAL** | $25.3 m |

[1] Totals may not equal the sum of components due to rounding.
[2] Labor costs pertain to systems, states and EPA. Costs include activities such as reading the rule, notifying systems selected to participate, sample collection, data review, reporting and record keeping.
[3] Non-labor costs would be incurred primarily by EPA and by very large and large PWSs. They include the cost of shipping samples to laboratories for testing and the cost of the laboratory analyses.

Additional details regarding EPA's cost assumptions and estimates can be found in the "DRAFT Information Collection Request for the Unregulated Contaminant Monitoring Rule (UCMR 4)" (USEPA, 2015a) ICR Number 2192.07, which presents estimated cost and burden for the 2017–2019 period, consistent with the 3-year time frame for ICRs. Estimates of costs over the entire 5-year UCMR 4 sequence of 2017–2021 are attached as an appendix to the ICR. Copies of the ICR and its appendix may be obtained from the EPA public docket for this proposed rule, under Docket ID No. EPA–HQ–OW–2015–0218.

## II. Background

*A. How has EPA implemented the unregulated contaminant monitoring program?*

EPA published the list of contaminants for the first UCMR (UCMR 1) in the **Federal Register** (FR) on September 17, 1999 (64 FR 50556, (USEPA, 1999)), the second UCMR (UCMR 2) on January 4, 2007 (72 FR 368, (USEPA, 2007)) and the third UCMR (UCMR 3) on May 2, 2012 (77 FR 26072, (USEPA, 2012c)). EPA established a three-tiered approach for monitoring contaminants under the UCMR program that takes into account the availability of analytical methods, the source of water supply and the contaminants likely to be found. Assessment Monitoring for "List 1" contaminants typically relies on analytical methods, techniques or technologies that are in common use by drinking water laboratories. Screening Survey monitoring for "List 2"

## Summary of Ohio HAB Response

**2010:** The beginning...

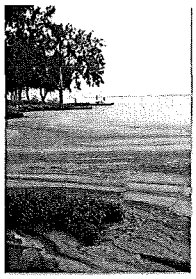
**2011:** Ohio HAB Response Strategy
- Record setting Lake Erie bloom

**2013** Finished water exceedance at small Public Water System (PWS)

**2014:** Finished water exceedance at large PWS

**2015:** U.S. EPA issued health advisory levels
- Ohio Senate Bill 1 passed in July
- Finished water microcystins detections at 5 PWSs
- OEPA began developing rules

**2016:** HAB Monitoring and Reporting Rules
- Effective June 1, 2016



Ohio Environmental Protection Agency

## July 2015 Ohio Lawmakers Pass SB 1 Key Drinking Water Provisions

- Ohio Revised Code 3745.50
- Director Ohio EPA - HAB management and response Coordinator
- Develop and implement protocols and actions including:
  - Analytical protocols
  - Health advisories
  - Public notification protocols
  - Training, testing, treatment and other support
  - Reporting requirements

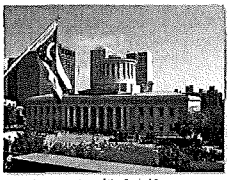


Image courtesy of the Capitol Square Review and Advisory Board

Ohio Environmental Protection Agency

## Applicability

- **Surface water systems**
  All requirements apply
- **Consecutive (purchased) surface water systems from out-of-state sources**
  Finished water microcystins monitoring only
- **In-State consecutive (purchased) surface water systems**
  Routine monitoring and treatment technique requirements do not apply; However, if wholesale system has action level exceedance then monitor at distribution sampling points.
- **Ground water systems**
  Routine monitoring requirements do not apply

Ohio Environmental Protection Agency

## Ohio HAB Rules Overview

- **PWS requirements** (OAC Chapter 3745-90)
  - Microcystins action levels in drinking water
  - Monitoring requirements: microcystins & cyanobacteria screening
  - Increased Monitoring Based on microcystin detections
  - Treatment technique requirements
  - Public notification (PN), Consumer Confidence Report (CCR), and recordkeeping requirements
- **Laboratory Certification requirements**
  (OAC rule 3745-90-04 and revised Chapter 3745-89)
  - Laboratory certification
  - Analytical techniques
  - Reporting deadlines

epa.ohio.gov/ddagw/rules.aspx

Ohio Environmental Protection Agency

# Microcystin Action Levels

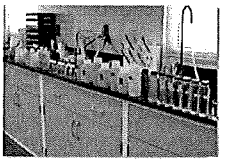
- **Based on U.S. EPA's health advisory levels which are based on oral ingestion of drinking water at these levels for up to ten days**

| Drinking Water Thresholds | Microcystins (µg/L) |
|---|---|
| Do Not Drink – children under 6 and sensitive populations* | 0.3 |
| Do Not Drink – children 6 and older and adults | 1.6 |

*Sensitive populations – nursing and pregnant women, individuals with liver disease, those on dialysis

Ohio Environmental Protection Agency

# Monitoring Requirements for Microcystins



- May – October: Weekly raw and finished water
- November – April: Reduced sampling (1 raw biweekly) if 2 consecutive weekly raw & finished show ND.
- Additional Sampling is Triggered:
  - Raw water detections >5 ug/L
  - finished water detections

*See, OAC Rule 3745-90-03(B) and (C) for consecutive system requirements.

Ohio Environmental Protection Agency

# Monitoring/Screening Requirements for Cyanobacteria

- **Cyanobacteria Screening**
  All year
  - Biweekly raw water
  - Triggers follow up sampling by OEPA for other cyanotoxins

Ohio Environmental Protection Agency

# Increased Monitoring Based on Microcystin Detections

- **Raw water > 5 ug/L** = increase monitoring to 3 days/week
- **Finished water detect** = increase to daily monitoring
- **Finished water detect exceeds Action Level**
  - **Resample:** collect raw and finished resample as soon as possible but no later than 24 hours after notified of exceedance. Analyze within 24 hours of collection
  - **Repeat:** collect raw and finished repeat samples within 24 hours of collecting the resample. Analysis of repeat sample must be completed within 24 hours of collection.

*Resamples and repeats count as daily monitoring.

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## Action Level Exceeded in Resample or Repeat

- **If any finished water Resample or Repeat samples exceed the action level:**
  - Notify any consecutive systems (w/in 3hrs of receiving resample or repeat results that exceed Action Level)
  - Collect distribution samples (including consecutive systems, w/in 24 hrs of receiving the resample or repeat results that exceed Action Level)
- **If finished water Repeat samples exceed the action level:**
  - Conduct public notification

Ohio Environmental Protection Agency

## Treatment Technique Requirements

- **Treatment Optimization Protocol** (short term)
  - Microcystins detected in raw or finished water
  - Within 30 days, submit Treatment Optimization Protocol
  - Optimize existing treatment
- **Cyanotoxin General Plan** (short term & long term)
  - Microcystins exceed 1.6 mg/L in raw more than once in consecutive 12 month period OR detections in finished water or distribution sample
  - Source water protection, reservoir management and in-plant treatment

Ohio Environmental Protection Agency

## Tier 1 Public Notice

- **Repeat finished water sample exceeds an action level**
- **Based on the results of resamples or distribution system samples, if required by the Director**
- **Failure to collect resample or repeat samples**

Ohio Environmental Protection Agency

## Tiers 2 & 3 PN, CCR

- **Tier 2 PN**
  - Failure to submit treatment optimization protocols
  - Failure to submit or implement cyanotoxin general plan
- **Tier 3 PN**
  - Failure to monitor or report
- **CCR**
  - Include any finished water action level exceedance (including distribution sites)

Ohio Environmental Protection Agency

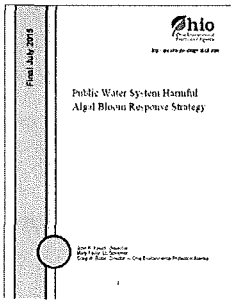
## Certified Lab Reporting Deadlines

- **Report by the end of the next business day to OEPA and PWS**
  - ➢ all detections of microcystins in finished water samples
  - ➢ all results above 5 µg/L microcystins in raw water samples
  - ➢ resamples and repeat samples after action level exceedance
  - ➢ all results of cyanobacteria screening that indicate the potential for cylindrospermopsin, saxitoxins, anatoxin-a
- **All others, report by the 10th day following the month in which the sample was collected.**

Ohio Environmental Protection Agency

## Integration of Rules with HAB Strategy

- HAB strategy updated to incorporate the required compliance monitoring
- Cyanobacteria screening will be used to determine if monitoring for cyanotoxins other than microcystins needs to be conducted by Ohio EPA (or voluntarily by the PWS)
- Thresholds for saxitoxin, cylindrospermopsin, anatoxin-a
- http://epa.ohio.gov/ddagw/HAB

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## Next Steps

- **Funding Assistance**
  - WSRLA HAB Infrastructure Loans (0% Interest/20 yrs)
  - Monitoring Equipment Grants – (up to $30K per PWS, lifetime max).
- **Ongoing Research**
  - Ohio Board of Higher Education HAB Grants
  - Collaboration with USEPA and AWWA on Methods
  - Collaboration with NOAA and USGS on HAB Surveillance
- **Post-Season full evaluation of 2016**

Ohio Environmental Protection Agency

Ohio Environmental Protection Agency

Division of Drinking and Ground Waters
March 2016

# Public Water System Harmful Algal Blooms – Overview of Upcoming Rules

## What are Harmful Algal Blooms?

Harmful Algal Blooms (HABs) are large growths of cyanobacteria (also referred to as blue-green algae) that can produce a variety of harmful chemicals known as cyanotoxins which can cause illness and death in humans and animals. These cyanotoxins include liver toxins, nerve toxins and skin toxins.

The United States Environmental Protection Agency (U.S. EPA) recently issued national health advisory levels for two cyanotoxins: microcystins and cylindrospermopsin. The health advisory values are based on oral ingestion of drinking water at these levels for up to 10 days.

| Cyanotoxin | 10-day health advisory level | |
|---|---|---|
| | Bottle-fed infants and pre-school children | School-age children and adults |
| microcystins | 0.3 µg/L | 1.6 µg/L |
| cylindrospermopsin | 0.7 µg/L | 3 µg/L |

## What will the HAB rules require?

The new rules in Chapter 3745-90 (Harmful Algal Blooms) of the Administrative Code and amended rules in Chapter 3745-89 (laboratory certification) will:

I. **Establish microcystins action levels in drinking water based on U.S. EPA's health advisory levels.**

II. **Establish monitoring requirements for public water systems using surface water including:**
   1. Routine biweekly cyanobacteria screening.
   2. Routine weekly source and finished water monitoring for microcystins from May 1 to October 31.
   3. Routine biweekly source water monitoring for microcystins November 1 through April 30 (microcystins detections will trigger increased monitoring).
   4. Increased monitoring based on detections of microcystins above 5 µg/L in the raw water (three days a week) or detection of microcystins in finished water (daily monitoring).
   5. Increased monitoring if an action level is exceeded in finished water:
      a. Resample within 24 hours of receiving the results of the initial action level exceedance;
      b. Repeat within 24 hours of receiving the resample results;
      c. If a resample or repeat sample exceeds the action level, notify any consecutive (purchased) water systems and collect distribution samples.
   6. Opportunity for decreased screening and monitoring schedule, depending on results.

III. **Establish treatment technique requirements:**
   1. If microcystins are detected in raw or finished drinking water, the water system will be required to develop and submit written cyanotoxin treatment optimization protocols.
   2. If microcystins exceed 1.6 µg/L in raw water on two or more occasions within a 12-month period or are detected in finished drinking water, the water system will be required to submit and implement an approved cyanotoxin general plan with one or a combination of source water protection activities, reservoir management and in-plant treatment technologies. In some instances, the general plan may document existing treatment is sufficient for cyanotoxin destruction or removal.

IV. **Require public notification for monitoring or reporting violations, treatment technique violations and exceedance of action levels in repeat samples of finished water; require action level exceedances to be included in consumer confidence reports.**

V. **Establish recordkeeping requirements.**

VI. **Establish requirements for laboratory certification, analytical techniques and reporting deadlines.**

# Public Water System Harmful Algal Blooms – Overview of Upcoming Rules

## Who will be affected by these rules?

These rules apply to all public water systems and certified laboratories, as follows:

Surface water systems

All of the above requirements apply to water systems which use surface water as a source.

Consecutive (purchased) water systems

The routine monitoring and treatment technique requirements do not apply to consecutive water systems that purchase water from an Ohio public water system. If their wholesale water system has an action level exceedance, consecutive systems may be required to conduct monitoring at distribution sampling points, issue public notification, include the exceedance in their Consumer Confidence Report and keep records. Consecutive water systems receiving water from an out-of-state surface water system are required to monitor their finished water for microcystins.

Ground water systems

The routine monitoring requirements do not apply to ground water systems. If samples collected voluntarily by a ground water system or Ohio EPA exceed an action level, the ground water system may be required to issue public notification, include the exceedance in their Consumer Confidence Report, fulfill treatment technique requirements and/or keep records.

Certified laboratories

These rules incorporate microcystins and cyanobacteria screening into the existing laboratory certification program. Laboratories granted acceptance in 2015 must submit new MDL results 30 days before the expiration date on the acceptance letter. Acceptance will be granted until one year from the rule's effective date. The $1,550 laboratory certification fee for these parameters will be deferred until one year from the rule's effective date. The approved analytical method for microcystins is Ohio EPA Total (Extracellular and Intracellular) Microcystins - ADDA by ELISA Analytical Methodology Ohio EPA DES 701.0 version 2.2 (November 2015). Ohio EPA may accept other analytical methods in the future. Microcystins samples must be analyzed within five days of collection, except in limited circumstances which require analysis within 24 hours.

Ohio EPA will be using quantitative polymerase chain reaction (qPCR) as a new method for cyanobacteria screening in lieu of algal identification. Ohio EPA's Division of Environmental Services (DES) intends to be prepared to certify laboratories in this method beginning in 2017. Until such time as there is sufficient capacity at certified laboratories to perform this method, DES will conduct the cyanobacteria screening required under these rules. Cyanobacteria screening samples must be analyzed within seven days of collection.

Results must be reported by the 10th day following the month in which the sample was collected, except for the following which must be reported by the end of the next business day: all detections of microcystins in finished water samples; all results above five micrograms per liter total microcystins in raw water samples; and all results of cyanobacteria screening that indicate the potential for production of cylindrospermopsin, saxitoxins or anatoxin-a.

## How will the rules and HAB strategy coordinate with each other?

Ohio EPA will update the HAB strategy to incorporate this regulatory approach to microcystins and cyanobacteria screening into the broader, statewide HAB program. The requirements for microcystins monitoring and associated potential requirements if an action level is exceeded will replace the approach to microcystins in the current HAB Strategy. With respect to the other cyanotoxins, the results of the cyanobacteria screening required by these rules will be used by Ohio EPA to determine if monitoring for cyanotoxins other than microcystins needs to be conducted by Ohio EPA (or voluntarily by the PWS). These results will provide additional data to determine the occurrence of these cyanotoxins and inform whether any future rulemaking for these parameters is warranted.

## What is the rulemaking process and schedule?

Ohio EPA plans to adopt final rules to be effective June 1, 2016.

## How can I get more information?

For more information visit the Ohio EPA website at ***epa.ohio.gov/ddagw/HAB.aspx*** or call (614) 644-2752.

# Harmful Algal Blooms and Human Health

Jason Huntley, Ph.D.
Associate Professor
University of Toledo, College of Medicine and Life Sciences

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IN
UT WATER TASK FORCE

## Focus Area: Toxicity, Microbiology, and Public Health

1. Detecting microcystin toxins in biological samples

2. Effects of microcystin toxin on the liver

3. Recreational exposure to cyanotoxins
   (April Ames & Mike Valigosky – Dept. Public Health)

4. Microcystin-detoxifying biofilters
   (Jason Huntley – Dept. Medical Microbiology & Immunology)

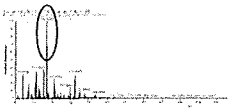
Project 1:

## Detecting Microcystin Toxins in Biological Samples

Ken Hensley (Pathology) & Dragan Isailovic (Chemistry & Biochemistry)

≠

Mass spectrometry

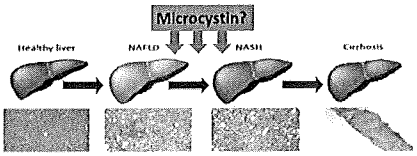


Project 2:

## Impact of Pre-Existing Liver Disease on Microcystin Hepatotoxicity

David Kennedy & Steven Haller (Medicine)

- Microcystin is a potent liver toxin
- 1/3rd of NW Ohioans affected by pre-existing non-alcoholic liver disease (NAFLD)
- Effect of NAFLD on susceptibility to microcystin toxicity is unknown
- Created mouse model of pre-existing liver disease and are exposing mice to microcystin

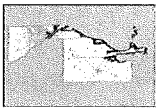



Project 3:

## Characterization of Recreational Exposures to Cyanotoxins in the Western Lake Erie Basin

April Ames & Michael Valigosky (Public Health)

- Survey recreational and occupational users of Lake Erie in Lucas, Ottawa and Sandusky counties
  1. Frequency, duration, exposure route(s)
  2. Geographical areas of use
  3. Activities for future air sampling
- Examine exposure and risk of recreational and occupational populations to aerosolized MC-LR

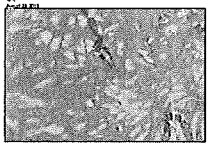


Project 4:

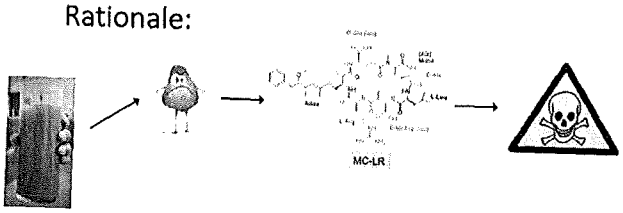
## Using Lake Erie Bacteria to Degrade Microcystin

Jason Huntley (Medical Microbiology & Immunology)

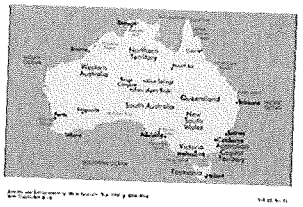




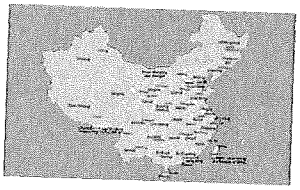
## Rationale:

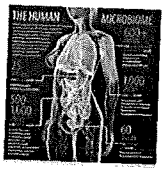



## Evidence for Microcystin-LR (MC-LR) Degradation

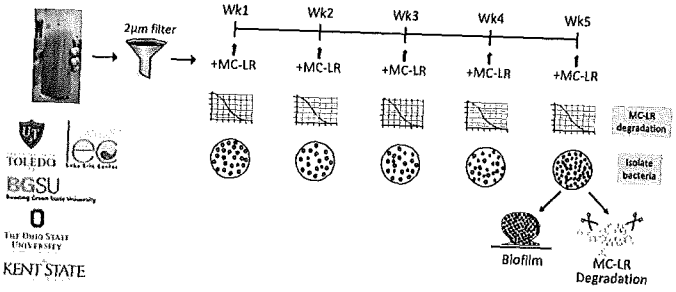


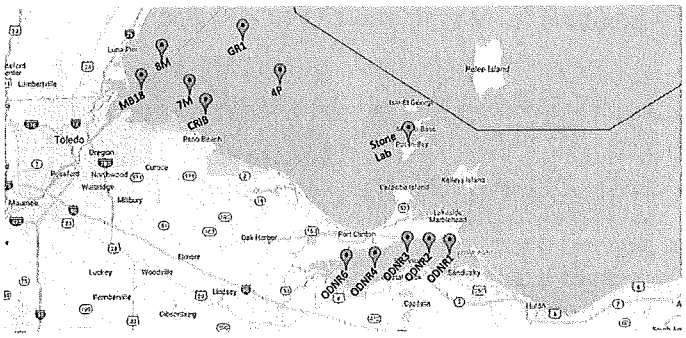
Enzymatic Pathway for the Bacterial Degradation of the Cyanobacterial Cyclic Peptide Toxin Microcystin LR



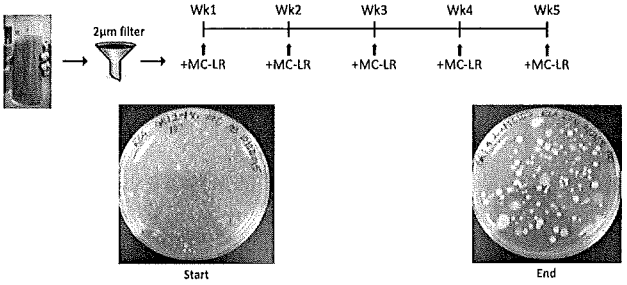




## Project Outline






# Selection for MC-LR Degraders

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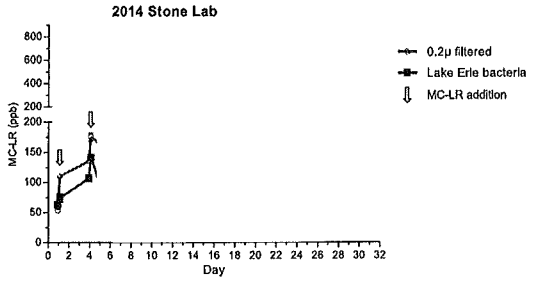


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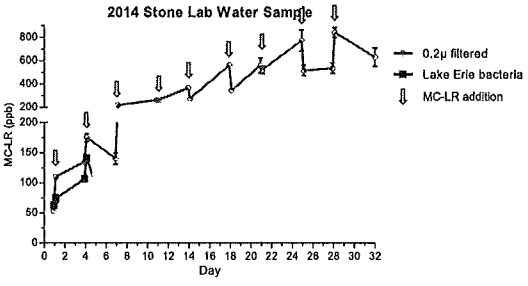
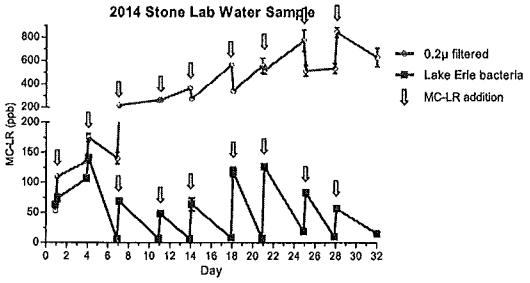
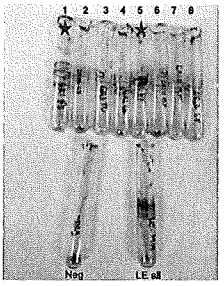
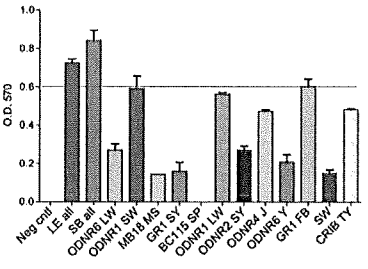


## Selection for MC-LR Degraders



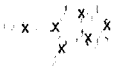

## Can MC-LR Degraders Form Biofilms?




## Current and Future Studies

- Testing individual clones and groups for MC-LR degradation
- Test biofilm formation on granulated activated charcoal (GAC)
- Lab-scale water purification to test biofilter efficiency
- Purify MC-LR degrading enzymes



## Acknowledgements

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