



**American Water Works  
Association**

*Dedicated to the World's Most Important Resource™*

Government Affairs Office  
1300 Eye Street NW  
Suite 701W  
Washington, DC 20005-3314  
T 202.628.8303  
F 202.628.2846

March 14, 2017

Health and Ecological Criteria Division  
Office of Water  
Environmental Protection Agency  
1300 Pennsylvania Avenue NW  
Washington, DC 20460

Re: Comments on EPA's *Health Recreational Ambient Water Quality  
Criteria and/or Swimming Advisories for Microcystins and  
Cylindrospermopsin* No. EPA-HQ-OW-2016-0715

Dear Sir or Madam:

The American Water Works Association (AWWA) appreciates the opportunity to comment on the Environmental Protection Agency's draft of *Health Recreational Ambient Water Quality Criteria and/or Swimming Advisories for Microcystins and Cylindrospermopsin*.

After reviewing the docket and gathering information from industry experts, we believe that EPA has not conducted all of the necessary analysis to assure that these criteria will protect public health, be implementable and be economically viable. Additional involvement of stakeholders and the public is necessary to assure that the final criteria will benefit public health.

**Clean Water Act criteria provide important protections for source water, but balance is needed**

AWWA has repeatedly urged EPA to utilize its Clean Water Act authority to protect public health particularly through measures that protect drinking water supplies. The public record for this proposal does not demonstrate how the proposed criteria will meet their objective, what situations would be impacted, nor the cost consequences, particularly given ongoing efforts to implement numeric nutrient criteria. For example, how would cyanotoxin ambient water quality criteria be used to improve management of nutrient loadings from non-point sources? And, conversely, how would these criteria affect NPDES permits, when there are already numeric nutrient criteria being applied?

## **EPA should re-examine the underlying toxicological information and its portrayal in this document**

A number of states, countries, and the World Health Organization have analyzed the risks posed by microcystin and or cylindrospermopsin. The EPA's analysis is markedly different from those of other authoritative bodies, including analyses with access to the same studies as EPA. These differences result from a series of risk assessment choices that when taken together lead to a markedly different conclusion than other risk assessments:

1. A single critical study which utilizes a particular rat breed,
2. Use of a secondary measure of toxicity without demonstrated linkage to direct measures of toxicological effect,
3. Not reducing the uncertainty factors when data is available related to mechanisms and modes of action for microcystin-LR, and
4. Deriving a level of concern for all microcystins as one similar group when the data is almost exclusively derived from microcystin-LR.

These challenges exist in the formulation of the drinking water health advisory published in 2015 and are relevant to the proposed values in this notice.

EPA's values for these recreational exposure criteria as well as the existing health advisories for drinking water (80 FR 34637-34638) have concentration levels of concern that are substantially lower than those set by other regulatory and scientific organizations and differ substantially in methodology. Other recreational levels of concern are referenced for microcystins in Tables 2-2 (international) and 2-3 (U.S. States), and in greater detail in Appendices A and B. As two examples, EPA's level of concern for microcystins in drinking water (based upon the same toxicological data as this proposal) differs substantially from those of the World Health Organization (WHO) and Australia. Although the document discusses the WHO methodology, it does not appear to try to reconcile why EPA's conclusions differ so much from WHO, Australia, several other countries, and several U.S. states. In order for EPA's conclusions to be credible when departing from established thresholds from other respected agencies, EPA should describe clearly the differences in methodology and data used and why the results are not similar, and should consider better aligning its methodology with those of other respected organizations, especially to the extent that these other organizations have already evaluated the underlying toxicological and exposure data. As part of this, EPA should reevaluate the underlying science to assure that the data utilized are truly the most appropriate, are replicable and otherwise considered of sufficient quality

for use in regulatory processes, and have correctly applied risk assessment methodologies. For example, in the Heinze et al (1999) study, the strain of rat used may have impaired liver function and be biased towards showing larger liver impairments than strains typically used in Agency risk assessments.<sup>1</sup> Given the importance of the decisions to be made with these criteria and with the existing health advisories, EPA should examine this and other issues to assure relative consistency among risk assessments and the underlying high quality science and appropriate use of it.

Although less data exists for cylindrospermopsin (for example, there are fewer international guidelines – such as an interim Australian guideline and one expected soon from WHO), EPA should nevertheless lay out in its methodology and how its result would likely differ from other respected organizations if they were to establish threshold values in the future. Additionally, the limitations of the scientific data should also be described clearly, and if insufficient scientific information is available to make this decision appropriately, a plan should be created for developing it.

### **EPA should better describe analytical methods and their limitations**

Relatively little discussion is included in this document as to analytical/detection methods. AWWA has found that there is considerable variability in the results amongst different analytical methods or even the same method at different laboratories for microcystins and cylindrospermopsin. For example, in 2007 and 2009 the Florida Department of Environmental Protection commissioned round-robin studies of laboratories<sup>2</sup> using several different microcystins analytical methods, and although the results were found to be excellent for the presence/absence of microcystins, replication of concentrations was very challenging.

In 2015 and 2016, Abraxis organized and performed two proficiency programs for ELISA-ADDA microcystin quantification in which 18 and 28 laboratories participated, respectively. These proficiency studies' reports summarized the results for the ELISA-ADDA workflow as; 1) a false positive (2015), 2) non MCLR concentrations ranged +/- 50% from the mean value, and 3) 10 out of 92 of the non

---

<sup>1</sup> Heinze 1999 utilized the first generation progeny of breeding pairs of female WELS/Fohm and male BDIX rats.

<sup>2</sup> Florida Department of Environmental Protection. July/August 2007 Microcystin Round Robin Study [http://dep.state.fl.us/labs/biology/hab/docs/microcystin\\_rr.pdf](http://dep.state.fl.us/labs/biology/hab/docs/microcystin_rr.pdf) and *January 2009 Microcystin Round Robin Study*. [http://www.dep.state.fl.us/labs//biology/hab/docs/microcystin\\_rr2v4.pdf](http://www.dep.state.fl.us/labs//biology/hab/docs/microcystin_rr2v4.pdf)

MCLR reported values were not within the proficient range. The non MCLR samples contained either LA, RR, or both RR and LR.<sup>3</sup>

EPA should review this document, cite it by clearly describing the challenges around analytical methods for microcystins, and re-evaluate these criteria based upon analytical challenges. The ELISA method is semi-quantitative. A recently study by the Metropolitan Water District of Southern California demonstrated +/- 25% method variability in the low drinking water HA range, and ELISA derived MC-LA concentrations were 2 to 3 fold higher than the spike concentrations using kit-provided MC-LR standards<sup>4</sup>. Although this concern is greater at and around the much lower levels of concern seen in the drinking water health advisories (as low as 0.3 µg/L for microcystins and 0.7 µg/L for cylindrospermopsin,) it nevertheless remains a key consideration at all concentrations. EPA should take the following actions:

1. Select or develop suitably quantified reliable analytical methods for use in water quality testing. Describe clearly the analytical methods for detecting microcystins and cylindrospermopsin in recreational waters. This analysis should with an emphasis on EPA standard methods and other methods that have been approved by independent agencies or organizations.
2. In describing the available analytical methods, clearly articulate the ranges of detection where these methods are known to be accurate (and conversely where their limitations are) and discuss how interpreting their results for lower levels of concern could be inaccurate.
3. Finally, describe clearly how and why levels found in ambient water (especially if the samples are lysed prior to analysis) could be substantially different than those found in treated drinking water using the same or nearby sources, to help prevent confusion and unnecessary alarm.

### **EPA should consider and describe CWA implementation for this criteria**

There are many implementation issues for this proposed criteria. In order to be effective and prevent confusion to the greatest extent possible, EPA should work with stakeholders to address implementation issues prior to finalizing this document.

Cyanobacteria blooms are not uniformly distributed and cyanotoxin production and accumulation is not uniform. This complicates sampling necessary to link

---

<sup>3</sup> Preliminary information from *Performance Evaluation Methods for Analysis of Cyanotoxins*. Expected Completion 2018. Water Research Foundation Project 4647. <http://www.waterrf.org/Pages/Projects.aspx?PID=4647>.

<sup>4</sup> Guo, Y, A.K. Lee, R.S. Yates, S. Liang, and P.A. Rochelle. March 2017. *Analysis of Microcystins in Drinking Water by ELISA and LC/MS/MS*. Journal – American Water Works Association, 109:3. DOI: <http://dx.doi.org/10.5942/jawwa.2017.109.0027>.

cyanotoxins to particular causes and make determinations on actions like beach closures. For a beach swimming advisory level, there are outstanding questions over sampling techniques, timing, responsibilities, interpretation of data and actions resulting from them, and costs and benefits of such programs. Recognizing that state and local agencies and not EPA will ultimately be making most of the decisions around these topics, EPA should nevertheless analyze all of these items for feasibility, costs and benefits, and present objective information and options from which state and local agencies can pick and choose the most appropriate and/or build different strategies.

For a CWA criterion, the implementation questions are more extensive. In addition to all of the items referenced above for beach advisories, there is also the question of how CWA mechanisms would work for microcystins and cylindrospermopsin. As the bacteria that generate microcystins and cylindrospermopsin grow in the environment due to underlying factors, a TMDL or other action would have to revolve around precursors that promote or lead to cyanobacterial blooms that ultimately release microcystins and cylindrospermopsin. For example, although it is well known that nutrients contribute to cyanobacterial blooms, in most cases it is not known precisely what level of nutrients will result in a bloom, and what factors will promote cyanotoxins production and release during a bloom. Similar nutrient loads in different years often result in different occurrences. These uncertainties do not mean that no action should be taken, but rather that these implementation issues should be explored fully and transparently working with partners prior to finalizing this report.

### **EPA should consider and discuss public engagement and public perception**

The level of scientific uncertainty around these recreational levels of concern is substantial and not well discussed in the document. EPA should explicitly state that its methodology generally assumes the most conservative value of each step along the process, resulting in an end-value that could be well below the actual level of concern. Additionally, EPA should consider and analyze the potential for misinterpretation of the value and instances where its intended use (or potential unintended uses) may cause unnecessary public concern or lead to unnecessary beach closures and other actions that could erode public confidence. With a thorough consideration and discussion of these factors, EPA can help prepare state and local authorities for potential issues surrounding the implementation of these criteria. This should be developed through an open and transparent stakeholder process to allow all perspectives and concerns to be brought to the table, considered, and discussed to allow development of strategies to mitigate them before state and local authorities are attempting to respond to the criteria directly. As an example, there may be instances where beaches and waterbodies close to drinking water

intakes are experiencing levels above the threshold, but the drinking water treatment is removing the cyanotoxins to an acceptable level, in which case there could be unwarranted concern focused on drinking water supplies due to these recreational criteria. This could also apply in cases where increased monitoring is taking place to address these criteria and the results fall below the levels of recreational concern but above the drinking water health advisory levels.

**EPA should more clearly analyze and discuss the public health, environmental, and economic impacts of these guidelines**

No analysis is presented in the docket on the costs of implementing these criteria for any of their intended uses, nor any discussion of the costs and benefits of beach closures and other activities under the Clean Water Act that could result from it if a state were to implement these criteria. Recognizing that states will need information in order to evaluate the possibility of implementing these as criteria, EPA should perform an economic assessment identifying costs and benefits. We recommend that EPA follow the White House Office of Management and Budget's recommendations for *Economically Significant Guidance Documents* to assure that all appropriate factors are considered. AWWA wrote a letter on July 2, 2015 (attached for reference) with regards to the document *Recommendation for Public Water Systems to Manage Cyanotoxins in Drinking Water* expressing these and other concerns. We believe many of the same concerns expressed in that letter would apply in this instance as well, given the possibility of beach closures and allocation of resources to address the recreational criteria. The results of this analysis can inform EPA as to whether there is or is not sufficient information to determine whether these criteria will be protective of public health and can be implemented in a reasonable, cost-effective manner.

**Additional Comments**

Numerous international criteria are referenced throughout the document from a 2012 German compilation report following an international conference. It is not clear whether EPA has verified that the information from this report is up to date and correct directly from each country's appropriate agency or publicly available information. WHO is in the process of reexamining its drinking water guideline and developing recreational water guidelines and will likely issue the revised guidelines by year end. It will likely include guidelines for long-term and short-term drinking water exposures and guidelines for recreational water exposures for several cyanotoxins. EPA should await the WHO review, whose committee has EPA participation before finalizing this assessment. In the meantime, it should reference the current guidelines from these agencies directly, rather than through a compilation report. With completion of the WHO review, EPA would also be in a position to review its current drinking water health advisory levels.

March 14, 2017

Page 7

EPA's attention to these important issues is essential and greatly appreciated. We appreciate the opportunity to comment on this important proposed rule. Please feel free to contact myself or Adam Carpenter at AWWA (202-628-8303, [acarpenter@awwa.org](mailto:acarpenter@awwa.org)) if you have any questions regarding this comment

Respectfully,

A handwritten signature in black ink that reads "G. Tracy Mehan, III". The signature is written in a cursive style with a large, sweeping "G" and a distinct "III" at the end.

G. Tracy Mehan, III  
Executive Director of Government Affairs  
American Water Works Association

cc: Peter Grevatt – USEPA OGWDW  
Andrew Sawyers – USEPA OWM  
Jamie Strong – USEPA OW  
Elizabeth (Betsy) Behl – USEPA OST  
Ryan Albert – USEPA OGWDW  
Lesley D'Anglada – USEPA OST

**About AWWA:**

AWWA is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founding 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes nearly 4,000 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our over 50,000 total memberships represent the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

Attachment: July 2, 2015 letter from AWWA to the U.S. EPA Office of Policy