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Adam Krantz

February 14, 2020

Mr. John Healey
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Mail Code 4305T
Washington, DC 20460
Submitted Via Email: wqs-implementation@epa.gov

***Re: NACWA Comments on EPA's Draft Technical Support Document:
Implementing the 2019 Recommended Human Health Recreational Ambient
Water Quality Criteria or Swimming Advisories for Microcystins and
Cylindrospermopsin (EPA 823-D-19-002)***

Dear Mr. Healey:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to provide comments on EPA's Draft Technical Support Document for Implementing the 2019 Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin (EPA 823-D-19-002). NACWA represents the interests of more than 330 public clean water utilities that are responsible for managing billions of gallons of the nation's wastewater generated each day to ensure the continued protection of public health and the environment.

NACWA provided comments to EPA on March 20, 2017 (please see attached) urging EPA not to issue final ambient water quality criteria (AWQC) for microcystins and cylindrospermopsin because of the inherent challenges associated with mitigating harmful algal bloom formation and cyanotoxin production for Clean Water Act (CWA) permittees, including publicly owned treatment works (POTWs) that typically do not discharge cyanotoxins. Specifically, NACWA raised concerns about how states would implement EPA's recommended AWQC given the complex site-specific water quality parameters and ecological factors that drive cyanobacterial blooms and toxin production. Rather, NACWA advocated that swimming advisory programs would offer the greatest public health protections.

EPA's Draft Technical Support Document provides useful background information and resources on these implementation challenges as well as highlight flexibilities states can choose when considering AWQC or swimming advisories (*e.g.*, the ability to define the length of the recreational season, revise the designated uses of waterbodies within their state, and derive site-specific criteria elements). However, NACWA continues to have concerns over how state regulators will handle implementation if they choose to adopt EPA's recommendations into their water quality standards, especially if actions lead to the development of numeric CWA permit limits. Such limits could present severe challenges for public clean water utilities.

A top priority for EPA as states to begin to evaluate their next steps is to approve an analytical method that meets the standardized data quality objectives in 40 CFR Part 136

to minimize inaccuracy or variability in cyanotoxin analysis. This is especially important since EPA itself states that “analytical results may vary depending on the analytical methods used” and that “the presence of cyanobacteria does not necessarily mean that cyanotoxins are being produced.” It is incumbent upon EPA to develop an analytical method that meets standards provided in Part 136 to ensure that CWA regulated entities have some comfort in the analytical results that will determine their compliance status. Given this reality, NACWA further urges EPA to require states to use toxin concentration rather than cyanobacterial cell density as the basis for determining whether there has been any exceedance in water quality compliance.

Thank you for your consideration of these comments. If you have any questions or would like to discuss these comments further, please contact me by phone at 202/533-1839 or email at eremmel@nacwa.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Emily Rimmel", with a stylized flourish at the end.

Emily Rimmel
Director of Regulatory Affairs

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Adam Krantz

March 20, 2017

Mr. John Ravenscroft
Health and Ecological Criteria Division
Office of Water (4304T)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Submitted Via the Federal eRulemaking Portal: <http://www.regulations.gov>

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

Dear Mr. Ravenscroft,

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the *Request for Scientific Views: Draft Human Health Recreational Ambient Water Quality Criteria and/or Swimming Advisories for Microcystins and Cylindrospermopsin* (EPA-HQ-OW-2016-0715).

NACWA represents the interests of nearly 300 public clean water utilities across the country who are helping ensure a strong, sustainable clean water future. NACWA's public clean water agencies treat and reclaim the majority of the wastewater generated each day nationwide, providing an essential service that protects human health and the environment.

NACWA understands the importance and need to protect human health from potential recreational exposure to toxic cyanobacterial blooms. Our members recognize that harmful algal blooms (HABs) have the potential to be a public health issue and can also have negative economic impacts. However, the clean water community will face considerable implementation challenges if these numeric criteria values are adopted as ambient water quality criteria (AWQC) and subsequently used as the basis for wastewater treatment permit limits that may not result in reduction of risk to human health or improve water quality.

EPA Should Not Issue Final Ambient Water Quality Criteria

EPA should not issue final AWQC for microcystins and cylindrospermopsin and should instead move forward only with guidance for states on

implementing swimming advisories if the Agency believes action regarding these cyanotoxins is necessary. AWQC are adopted by regulators to set target levels for a particular pollutant in the water environment and to support inclusion of Clean Water Act (CWA) permit limits to address that pollutant. EPA should not adopt AWQC for cyanotoxins because of the implications they will have for CWA permittees, including publicly owned treatment works (POTWs), none of which actually discharge cyanotoxins. Permit limits for cyanotoxins are illogical and establishing AWQC for cyanotoxins will not help to reduce or eliminate cyanotoxins in the environment or the potential for cyanotoxin presence instream. Rather, EPA must focus on addressing the causal variables of cyanobacteria blooms that produce toxins.

If adopted as AWQC, the values have the potential to cause considerable impacts on the municipal clean water community especially if authorized states somehow incorporate the numeric criteria into existing or future CWA permits as limits. As discussed below, NACWA has concerns with how permit limits and conditions will be written to address these criteria, especially since POTWs do not actually discharge cyanotoxins. AWQC values are regulatory in nature and have significant regulatory and potentially legal consequences under the CWA. Imposing burdensome permit requirements on dischargers with no certainty that the limits will help to reduce cyanobacterial bloom formation or eliminate cyanotoxins in surface waters is unnecessary and unreasonable.

Again, if EPA feels action is needed, it should only recommend swimming advisory values for states to consider as a mechanism for notification purposes to protect public health and welfare.

Swimming advisories are effective means of providing notice to the general public to protect humans and pets from primary contact with water contaminated with cyanobacteria and possibly cyanotoxins. In fact, as EPA points out in the Draft Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin (EPA-822-P-16-002, hereafter Draft Cyanotoxin Criteria), “approximately 30 states have implemented cyanobacterial HAB guidelines for recreational waterways” as of late 2015. This raises the question as to why EPA feels obligated to publish national numeric criteria or even swimming advisories.

EPA Should Highlight Option to Elect Swimming Advisories Over AWQC

If EPA proceeds to publish the values for microcystin and cylindrospermopsin as both AWQC and swimming advisories, EPA should more clearly highlight that states will have the option to adopt only the swimming advisories, without also adopting the AWQC. It is NACWA’s understanding that in doing so, states that elect to adopt swimming advisories—and not the AWQC values—will satisfy EPA during the triennial review process. In other words, EPA should clarify that states electing to follow the swimming advisories or their own existing criteria and not adopt the AWQC, will not be pressured into adopting the federal AWQC.

Draft Criteria Fail to Consider Implementation

EPA’s *Request for Scientific Views* does not consider how regulators will implement or execute an AWQC established for microcystin or cylindrospermopsin. The relationships between blooms, toxin production and concentrations, and the causal variables associated with blooms and toxin production are extremely complex and site specific. Cyanobacteria blooms and associated cyanotoxins vary spatially and temporally. Biotic (e.g., grazers, competing algae) and abiotic factors (e.g., temperature, light, pH, hydrology, wet-dry weather patterns, currents, and turbidity) significantly influence cyanobacterial community formation and microcystin and cylindrospermopsin production/toxicity.

For these reasons, establishing AWQC-based permit requirements for POTW National Pollutant Discharge Elimination System (NPDES) permittees that reduce toxic cyanobacteria blooms and toxin concentrations will be difficult, if not impossible, to develop. In addition, given the complex variables that influence how nitrogen

and phosphorus impact the aquatic environment, attempting to use the total maximum daily load (TMDL) approach of controlling a pollutant in discharges to effect an outcome with a different parameter (in this case, controlling nitrogen and or phosphorus for POTW NPDES permittees to reduce the formation of cyanobacteria/cyanotoxins) will also not be reliably effective in meeting water quality goals.

EPA's original intent was focused, presumably, on protecting the public from contact with cyanotoxins during recreation. Because of the complexities in relationships between toxins, blooms, and numerous field variables as well as implementation of AWQC for cyanotoxins, EPA's objectives would be best met by publishing the swimming advisory levels and abandoning its effort to publish AWQC numeric criteria for microcystin and cylindrospermopsin.

EPA Must Have a Standard Protocol for Sampling and Analyzing Cyanotoxins

If EPA publishes the numeric criteria as AWQC, EPA must have standard sampling and analytical methods in place for the regulated community to use when monitoring or testing water samples. Scientific studies have demonstrated the linkage between cyanobacteria concentrations in water and subsequent toxicity, but there is considerable variability of cyanobacteria concentration and toxicity within a single water source and a single cyanobacteria bloom.

To illustrate this, several round-robin studies were conducted by the Florida Department of Environmental Protection demonstrating the wide variability of results both within and between laboratories for a single water sample. The study shows exactly how difficult it is to receive consistent, accurate data that are both quantitative and qualitative of cyanobacterial algal blooms and toxicity because of differences in laboratory methods. Even with a certified standard for microcystin congeners using the ELISA kit, the results showed wide variety within each testing sample and between laboratories. If it chooses to finalize the AWQC, EPA must consider and address how microcystins and cylindrospermopsin—especially given the potential for states to use these values as the basis for permit limits—would be sampled and analyzed given the extreme variation not only within a single water sample but also between laboratories.

More Peer-Reviewed Scientific Studies are Needed

The science is unsettled with respect to the relationship between cyanobacteria toxicity and human health. The Association is concerned with the limited number of peer reviewed scientific studies EPA used to ultimately derive the swimming advisories and recreational water quality criteria. In addition, the limits recommended by EPA do not appear to be based on any dose-response data from ambient exposures (*see Draft Cyanotoxin Criteria* pp. 46-47). Given the potential implementation burdens for the regulated community, more peer-reviewed scientific studies on cyanotoxins and human health are warranted.

Specific Comments

- The fate and transport of toxins in flowing rivers is different than the fate and transport in lakes. Accordingly, data regarding the toxicity of cyanotoxins based solely on exposures in lakes does not necessarily apply to exposures in rivers, where the residence time and concentration of those toxins may differ. Despite these differences and the lack of data from river systems, the cyanotoxin criteria recommended by EPA in its draft document would apply to all waterways.
- **Section 4.2.1 Approach for Recreational Ambient Water Quality Criteria Derivation**
The recreational AWQC for microcystin and cylindrospermopsin are calculated as described in the 2000 Human Health Methodology. The report states that the relative source contribution ("RSC") used in the equation is discussed in section 4.2.5. There is no section 4.2.5 in the report. EPA should clarify that it intended to reference section 4.2.4.

- **Section 4.2.3 Measures of Exposure**

EPA recommends that risk assessments use a 97th percentile value of 0.12 L/hour (120 mL) for children and 0.071 L/hour (71 mL) ingestion rate based only on the Dufour et al. (2006) small-scale pilot study (EPA suggests that other studies report similar results as Dufour). Yet, the Dufour study only included a limited number of participants (n=53) and, although other studies—Evans (n=>500), Dorevitch (n=3,367), Schets (n=8,000)—agree with Dufour that children ingest more water than adults, the ingestion rates vary from study to study.

Additionally, EPA disregards its most recent values for mean swimming duration. The 1997 and 2011 editions of EPA's *Exposure Factors Handbook* provide different values for mean swimming duration. Indeed, the 1997 edition provides values for time spent in a swimming pool/spa per day, while the 2011 edition provides values for time spent swimming (generally) per month.

EPA's Draft Cyanotoxin Criteria initially converted the 2011 edition's monthly swimming durations from months to days, which resulted in a very short daily exposure. Because this short duration did not "seem reasonable," EPA reverted back to the values in the 1997 edition which measured time spent in a pool/spa and resulted in 2.7 hours per day for children 5-11 years old.

This approach has questionable scientific merit because it utilizes 20-year-old exposure estimates for time spent in a pool/spa, rather than the more relevant general swimming metric set forth in EPA's more recent *Exposure Factors Handbook*.

- **Section 4.2.3.1 Incidental Ingestion**

EPA determined that using a swimmer scenario for exposure as the basis for the criteria will be protective of other aquatic activities. Although studies cited in this report used different methodologies, numbers of participants, and age groups, most agree that children ingest more water than adults. However, ingestion rates varied.

Mean ingestion rates for children ranged from 26 mL/hour (Suppes, 2014) to 63 mL/hour (Evans, 2006). Mean rates for adults varied from 3.5 mL/hour (Suppes, 2014) to 32 mL/hour (Evans, 2006). In addition, most of the studies are based on swimming in pools. Only one study (Schets, 2011) estimated ingestion rates based on swimming in fresh and marine surface water (28 and 29 mL/hour for children swimming in fresh and marine water respectively; 30 and 36 mL/hour for adult males and 20 and 26 mL/hour for adult females).

- **Section 5.1.1.2 Human Studies**

There are limited human studies examining microcystin's effects on humans. EPA's Draft Cyanotoxin Criteria discusses those studies, but none support the aggressive limit proposed by the Agency. For example, Backer et al. (2008) reported that recreational users in a lake at the time of an algal bloom had no detectable microcystins in their blood and did not report an increase in symptoms. This is true despite the fact that microcystin levels ranged from 2 to 5 µg/L.

In a later study by Backer et al. (2010), no statistically significant differences were noted in the frequency of reported symptoms between participants recreating in a lake with a cyanobacterial bloom and those recreating in a lake without a cyanobacterial bloom. In that case, microcystin concentration ranged from < 2 to >10 µg/L. Furthermore, in Lévesque et al. (2014), no associations were observed between any symptom and recreational exposures to microcystins.

Additionally, although Giannuzzi et al. (2011) reported that a single person immersed for 4 hours in a *Microcystis* bloom did exhibit symptoms of microcystin exposure. However, the microcystin concentration detected in Giannuzzi et al. (2011) was over 10 times higher than the limit now proposed by EPA. Similarly, in the 9 cases reported by Dziuban et al. (2006) and Hilborn et al. (2014), microcystin was measured at 5 times the level proposed by EPA. Moreover, that report cautioned that the results reported from the outbreaks should not be interpreted as cause and effect.

As for cylindrospermopsin, EPA is admittedly unaware of any epidemiological studies for recreational exposure to that toxin. Yet, despite this lack of data, EPA has nevertheless proposed stringent new limits for recreational exposure to cylindrospermopsin.

- **Section 6.3 Recommended Swimming Advisory and Recreational Criteria for Microcystins and Cylindrospermopsin**

EPA fails to establish a direct quantitative value between levels of nutrients and levels of cyanotoxin. Without this level of quantification, it is not scientifically defensible to impose nutrient limits on permittees based on EPA's proposed new cyanotoxin criteria.

Conclusion

NACWA recommends that EPA not proceed to finalize the AWQC for microcystin and cylindrospermopsin. If the Agency believes it is necessary, NACWA recommends that EPA instead move forward only with publishing the swimming advisories as guidance for states to protect human health from primary contact exposure to cyanotoxins. POTWs are not directly discharging cyanotoxins and, if AWQC are finalized and used as the basis for NPDES permit limits, they could create considerable implementation challenges for the municipal clean water community. If states choose to adopt the swimming advisories only, EPA must make clear that this will satisfy the Agency during the triennial review process.

If EPA does move forward with publishing AWQC for cyanotoxins, EPA must provide clear guidance on how states are to apply these values in the permitting context. In addition, EPA must specifically address how states and/or the regulated community are to quantify and qualify toxicity in their samples given the variability and inconsistencies in analytical techniques.

Thank you for your consideration of these comments. Please contact me by phone at 202/533-1839 or by email at eremmel@nacwa.org with any questions.

Sincerely,



Emily Remmel
Director, Regulatory Affairs