March 20, 2017

Mr. John Ravenscroft
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Filed via http://www.regulations.gov

Re: **Docket ID No. EPA-HQ-OW-2016-0751**
Draft Human Health Recreational Ambient Water Quality Criteria and/or Swimming Advisories for Microcystins and Cylindrospermopsin, 81 Fed. Reg. 91,929 (Dec. 19, 2016)

The agricultural and forestry organizations listed below provide these comments on EPA's "Draft Human Health Recreational Ambient Water Quality Criteria and/or Swimming Advisories for Microcystins and Cylindrospermopsin," EPA- 822-P-16-002 ("Draft Criteria"). EPA published a Notice of Availability and Request for Scientific Views related to the Draft Criteria in the *Federal Register* on December 19, 2016, and EPA invited the public to comment over the next 60 days. *See* 81 Fed. Reg. 91,929. EPA extended the public comment period by 31 days on February 15, 2017, until March 20, 2017. *See* 82 Fed. Reg. 10,766.

The undersigned organizations, or their members, own, operate, or have an interest in lands and facilities that produce or contribute to the production of the row crops, forests, livestock, and poultry that provide safe and affordable food, fiber, and fuel to Americans all across the United States. Many of their members hold individual and/or general Clean Water Act permits that regulate the discharge of pollutants into water, as well as those that undertake voluntary actions to control nonpoint source runoff of pollutants from their lands. The undersigned, or their members, are directly affected by regulatory and policy decisions under the Clean Water Act, particularly decisions aimed at controlling nutrients using Clean Water Act tools. Any proposed national recommended water quality criteria (or swimming advisories) that are ultimately intended to influence regulatory requirements associated with cyanotoxins or nutrients are of interest to the undersigned organizations.

Executive Summary

The undersigned organizations are troubled by EPA's decision to charge forward with issuing recommended values for microcystin and cylindrospermopsin pursuant to Clean Water Act Section 304(a), given our serious concerns with the science underlying the

Draft Criteria. We do not believe EPA should finalize its recommended values unless and until it addresses gaps in the scientific data and reasoning. Based on our review of EPA's Draft Criteria, the underlying documents, and comments submitted to the docket thus far by others, we offer the following comments:

- EPA does not appear to have considered whether recommended 304(a) criteria will actually result in effective management strategies to protect or restore the designated beneficial uses – in this case swimming in the absence of harmful algal blooms (HABs).
- EPA characterizes the draft as recommending water quality criteria under CWA Section 304(a) or swimming advisory levels. If EPA insists on finalizing any recommendations in the face of scientific uncertainty, it should publish only swimming advisories as Section 304(a)(2) "information," and it should *not* publish Section 304(a)(1) criteria.
- EPA should not recommend 304(a) criteria until adequate, peer-reviewed, scientific information is provided.
- EPA did not provide adequate explanation of the underlying criteria components and how it derived the Draft Criteria.
- If the agency feels compelled to develop recommended 304(a) criteria for recreational exposure to algal toxins for regulatory purposes, then the agency must engage scientists, policy makers, and other stakeholders in the development of the criteria and implementation guidance.
- If the agency instead wants to provide guidance to protect public health from exposure to algal toxins during recreation at freshwater and marine beaches, EPA should collaborate with states that have developed such guidance and publish a more useful, comprehensive Swimming Advisory document.
- Implementation of these levels as 304(a) criteria is going to be extremely complex, even more so than EPA's recommended ammonia criteria published in 2013 and only adopted by a handful of states primarily due to implementation issues. EPA should not promulgate these levels as 304(a) criteria until these implementation issues have been vetted.

While serious human health effects associated with recreational exposure to cyanotoxins can exist, promulgating CWA Section 304(a) criteria for two cyanotoxins will result in very expensive regulatory programs where it will be difficult to assess effectiveness in improving public health protection. As science and our understanding of mans' impact on our nation's water resources become more sophisticated, it is time for EPA to collaborate with states and other stakeholders to develop more effective approaches to implementing the CWA than churning out more 304(a) criteria, based on limited information, that cannot be met with available resources, including even the most

advanced technologies. EPA has the opportunity to use its resources to take advantage of new approaches to environmental strategies to protect public health from HABs – including crowdsourcing such as bloomWatch[1], rapid testing, and education.

Detailed Comments

1. **EPA does not appear to have considered whether these 304(a) criteria will actually result in effective management strategies to protect or restore the designated beneficial uses – in this case swimming in the absence of harmful algal blooms (HABs).**

The Draft Criteria only address two specific algal toxins associated with harmful algal blooms (HABs). However, the most effective strategy for reducing illnesses associated with exposure to cyanotoxins while swimming may be effective public reporting of HABs and public education.

When Congress enacted the Clean Water Act in 1972, it directed EPA to develop and publish criteria in the context of a continual planning process that included point and nonpoint source controls to control and (in some cases) eliminate the discharge of pollutants that were causing criteria to be exceeded. Nutrients (nitrogen and phosphorus) are the two pollutants that are in large part associated with HABs. Yet EPA and the states already have a comprehensive framework in place to address nutrient pollution.[2] And states are indeed taking the initiative to do so, as evidenced by the various HAB guidelines that the majority of states already have in place. Moreover, the formation of HABs is highly dependent on a variety of factors, such as environmental conditions or other sources including nutrients in sediments. Committing (potentially significant) resources to controlling pollution from point and nonpoint sources may not actually solve the HAB problem in a particular waterbody.

Watershed programs to prevent HABs are complex and generally require adequate monitoring, modeling, planning, stakeholder involvement, and resources. In some instances, even the most effective point and nonpoint source controls simply will not be sufficient to prevent HABs.

[1] *See* http://cyanos.org/bloomwatch/

[2] Stoner, N.K. Memorandum to Regional Administrators, Regions 1-10, Working in Partnership with States to Address Phosphorus and Nitrogen Pollution through Use of a Framework for State Nutrient Reductions (March 16, 2011); *see also* Beauvais, J. Memorandum to State Environmental Commissioners, State Water Directors, Renewed Call to Action to Reduce Nutrient Pollution and Support for Incremental Actions to Protect Water Quality and Public Health (Sept. 22, 2016).

2. EPA characterizes the draft as recommending water quality criteria under CWA Section 304(a) or swimming advisory levels. If EPA insists on finalizing any recommendations in the face of scientific uncertainty, it should publish only swimming advisories as Section 304(a)(2) "information," and it should *not* publish Section 304(a)(1) criteria."

To be clear, the undersigned organizations do not believe that the science supports the issuance of EPA's recommended values. Should EPA nevertheless ultimately decide to publish final recommended values for states to consider, it should do so strictly as "information . . . on the factors necessary . . . to allow recreational activities in and on the water" under Clean Water Act Section 304(a)(2). *See* 33 U.S.C. § 1314(a)(2). Such "information" is purely advisory in nature, though states remain free to use the EPA-recommended values as water quality standards should they so choose. If EPA is sincere about leaving states that choice, as the Draft Criteria suggests, the Agency should *not* take action under Section 304(a)(1). By publishing the recommended values as Section 304(a) "criteria," EPA is effectively placing its thumb on the scale. This is because, since 2015, EPA's amended water quality regulations (40 C.F.R. pt. 131) require states to adopt EPA's Section 304(a) criteria or provide an explanation for not doing so. *See* 40 C.F.R. § 131.20(a).

Interestingly, the Draft Criteria is inconsistent about whether EPA intends to finalize 304(a) criteria or whether it may only finalize swimming advisories. The title of the document and portions of it refer to both ambient water quality criteria and swimming advisories. Similarly, a February 2017 pre-publication draft of Chapter 3 of EPA's Water Quality Standards handbook describes these as draft 304(a) criteria. By contrast, other parts of the draft microcystins and cylindrospermopsin criteria/swimming advisories document seem to focus only on swimming advisories and even refer to swimming advisories in some places as being the sole purpose of the document. Again, we urge EPA not to finalize 304(a) criteria and to instead focus on recommending swimming advisories as 304(a)(2) information.

3. EPA should not recommend 304(a) criteria until adequate, peer-reviewed, scientific information is provided.

At this time, it does not appear as though there is sufficient data to support establishing recommended 304(a) criteria for states to potentially adopt as regulatory standards. EPA notes (in the executive summary, at 2) that the recommended values for use as swimming advisories and/or water quality standards "leverage the information collected and evaluated in EPA's *Drinking Water Health Advisory for the Cyanobacteria Microcystins Toxins*. Yet that document candidly acknowledges, also in its executive summary (emphasis added), as follows:

> 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.

Furthermore, EPA's drinking water health advisory document relies on laboratory studies linking liver and kidney damage in rodents from oral ingestion of drinking water. Perhaps that explains why EPA cannot point to compelling information in the Draft Criteria that ties the purported human health effects (damage to liver and kidneys) to actual exposure and illness rates associated with swimming in recreational waters. Nor does it seem that any pertinent studies on microcystin have been published after the drinking water health advisory. Indeed, there is only one study—Soller JA et al. (2016)—cited in the Draft Criteria that appears to have been published since EPA released its drinking water health advisory. That study is limited to fecal indicator bacteria and the risk of gastrointestinal illness; it does not address any of the aforementioned health effects.

In addition to citing the drinking water advisory, the Draft Criteria also cites the health effects support document for microcystin,[3] but that support document cites only five indirect studies attempting to link microcystin to liver and kidney damage:

- The Armidale, Australia study found a significant increase of a plasma enzyme (GGT) in an unknown number of patients exposed to a public water supply where a bloom was treated with copper sulfate (which can also be a liver toxin). It should be noted that 7-10% of the study population was alcoholics, which can contribute to increase of GGT.

- Army canoe exercise outbreak study – two out of 18 soldiers became very ill after canoeing in a reservoir with a bloom, but neither solider showed increased liver enzymes. No liver data were summarized for the other soldiers.

- In a study in China, the authors concluded that children had a greater risk of liver damage from Hepatitis B rather than from exposure to microcystin in drinking water and food (carp and duck) (cited at 31-33).

- Two studies in Brazil involved intravenous exposure of dialysis patients due to contaminated filters, not drinking water or recreational use-related exposures.

The Draft Criteria also cites a health effects support document for cylindrospermopsin.[4] Like the support document for microcystin, the support document for

[3] EPA (2015). Health Effects Support Document for the Cyanobacterial Toxin Microcystins. EPA-820R15102. Office of Water. June 2015.

cylindrospermopsin lacks sufficient data to conclude that there is a human health risk from exposure to cylindrospermopsin:

- The document notes that cylindrospermopsin seems to readily break down in sunlight (reported half-lives of 1.5 and 3 hours) when cell pigments are present (page 8). The document further states that "[t]he available toxicokinetic data for cylindrospermopsin are from studies that do not reflect environmental exposure conditions. All studies identified for this assessment were generated using intraperitoneal (i.p) exposures to mice or in vitro assays rather than by the oral, dermal and/or inhalation routes applicable to humans and domestic animals" (page 15).

- The document cites only one oral case study cited (from Palm Island in Queensland, Australia) documenting illnesses. There, a reservoir was treated with an unknown quantity of copper sulfate (which can cause liver damage) prior to the health outbreak.

- There were two dermal studies cited in the support document. In the first study, researchers were not able to identify a threshold level and in the second study there were no detectable skin reactions (pages 18 and 19).

- While there are a number of studies of health effects in mice that indicated liver and kidney damage from exposure to cylindrospermopsin, the mechanism for liver and kidney toxicity remains unknown (page 41).

Apart from the foregoing limitations in the data, EPA seems to be entering new territory by blending non-regulatory health advisories for short-term exposure to microcystin in drinking water with Clean Water Act criteria for fecal indicator bacteria at freshwater and marine beaches. The agency is then extrapolating from that to address cylindrospermopsin. EPA should provide a clear explanation for why this is appropriate and how it will result in increased protection of human health. Such an explanation is especially warranted given that the drinking water health advisory for microcystins indicates that insufficient data exist to establish recreational criteria.

The Draft Criteria are based on single animal studies involving ingestion of drinking water with constant levels of algal toxins for 28 days (microcystin) and 77 days (cylindrospermopsin), which were used to establish 10-day health advisories for drinking water. That prior approach, however, is inconsistent with risks associated with a single day, or even several days, of recreational exposure.

[4] EPA (2015). Health Effects Support Document for the Cyanobacterial Toxin Cylindrospermopsin. EPA-820R15103. Office of Water. June 2015.

4. EPA did not provide adequate explanation of the underlying criteria components and how it derived the draft criteria.

Not only are the data insufficient to conclude that there are human health risks from recreational exposure to microcystin and cylindrospermopsin, EPA's draft criteria document does not explain how the duration (recreation season) and frequency (no more than 10 percent of the days), which were considered for gastrointestinal illness from recreational exposure to fecal indicator bacteria, would be appropriate to use even if there were sufficient data to link liver damage to recreational exposure to algal toxins.

Interestingly, when EPA was deriving the recreational criteria for fecal indicator bacteria, the agency appeared to be relying on a duration of an entire recreation season (rather than the 30-day period that was ultimately adopted) and a frequency of exceedance of no more than 25 percent (rather than 10 percent) of days in the period. Yet the duration and frequency were changed at the very end of the 3-year development period with inadequate explanation by EPA staff.

Here, EPA has likewise provided inadequate justifications for the duration and frequency values that it has arrived at. With respect to duration, there are parts of the recreation season where algal toxins are likely to be less prevalent. Yet specifying the duration as one recreation season wrongly assumes that there is an equal likelihood of toxins across the entire recreation season. Equally important, using a duration of an entire recreation season seems inconsistent with the two studies that EPA cites to support establishing the non-cancer health effects of the two algal toxins. For microcystin, the study that EPA relies on was a 28-day exposure of rats to drinking water containing microcystin. For cylindrospermopsin, the study used a 77-day (11 week) exposure of mice. EPA needs to explain how prolonged exposure of toxic drinking water in rodents, who are provided no other source of drinking water, compares to incidental ingestion by children recreating in waters that are visibly contaminated with cyanobacteria.

Furthermore many of the scientific studies cited in the draft criteria document were based on small sample sizes or inconsistent ages, or they lacked comparative information. These shortcomings introduce statistical weaknesses, which have not been shared with the public. In particular, EPA selected 0.33 liters per day as the recreational water incidental ingestion rate for children, which appears to be conservative based on the calculations. This assumption was based on the following:

- EPA used an assumed 2.7 hours per day (at 38) spent swimming by children. This value, which comes from the 1997 *Exposure Factors Handbook*, Table 15-119, is based on the amount of time that children ages 5 to 11 spent in a home swimming pool or spa. The mean value of 2.7 hours per day (164.2 minutes) was based on a sample size of only 15 children, with a standard deviation of 103 minutes. It seems unrealistic that this exposure rate is appropriate for natural water bodies throughout the United States regardless of site-specific water temperature and current patterns. Interestingly, EPA's 2011 *Exposure Factors*

Handbook contained far lower daily durations, which EPA declined to use for purposes of this draft criteria document. Rather than simply papering over that discrepancy, EPA should explain in more detail why the 2011 durations were unreasonable.

- EPA assumed that a child would consume 0.12 liters per hour (L/hr) while swimming. This assumption is based on the 97% incidental ingestion volume for children aged 6 to 17 from the 2011 *Exposure Factors Handbook*, which in turn cites a Dufour et al. (2006) study. *See* Draft criteria at 40. Notably, the Dufour study was a pilot study which used the upper percentile due to the limited sample size (which included 41 children). Swimmers were limited to a 45-minute period for calculating the ingestion rate. Based on the information presented in Section 7.3 of the draft criteria document (at 60-65), the value from the Dufour study appears to be overly conservative. While the studies cited in Section 7.3 do confirm Dufour's findings that children tend to ingest more than adults (at 65), the related studies seem to suggest a lower ingestion rate could be appropriate. For instance, Suppes et al. (2014), had a mean rate of 0.026 L/hr with a maximum of 0.106 L/hr for 16 children aged 5 to 17. Moreover, EPA's Office of Pesticide Programs uses 0.050 L/hr based on the assumption that non-competitive, adult swimmers ingest twice as much as competitive swimmers and that children ingest twice as much as (non-competitive) adults. These values are based on EPA's Risk Assessment Guidance for Superfund.

EPA selected a reference dose of 0.05 micrograms per kilogram per day of microcystin. This was based on studies of different rats drinking water containing various levels of microcystin-LR (the most toxic congener) over a 28-day period.

The 2015 Health Effects Support Document for the Cyanobacterial Toxin Cylindrospermopsin calculated a reference dose with a "300x" safety factor (page 45) to account for interspecies variability and differences as well as database uncertainties.

EPA also determined (at 44) that children are being exposed to microcystin from other sources such as "fish and shellfish consumption, non-fish food consumption (*e.g.*, fruits, vegetables, grains, meats, poultry, dietary supplements), dermal exposure, and respiratory exposure." This is based on the "ceiling" of a Relative Source Contribution (RSC) of 80 percent in the EPA document entitled Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). That document was updated to incorporate new studies on water consumption and fish tissue consumption. EPA states that "although EPA will not use this intake parameter [incidental ingestion] when deriving its national 304(a) chemical criteria, limited guidance is provided in the Exposure Assessment TSD volume in order to assist States and authorized Tribes that face situations where this intake parameter could be of significance" (page 4-3).

In summary, the draft criteria document does not adequately explain EPA's reasoning for deriving the recommended values. There are gaps in the record that EPA must address before moving forward with any final recommendations.

5. **If the agency feels compelled to develop 304(a) criteria for recreational exposure to algal toxins for regulatory purposes, then the agency must engage scientists, policy makers, and other stakeholders in the development of the criteria and implementation guidance.**

EPA's court-ordered[5] process for updating its 304(a) recreational water quality criteria for pathogens and pathogen indicators included an Expert's Scientific Workshop to define a Critical Path Science Plan to guide studies and development of criteria; epidemiological studies with peer-reviewed, published research; multiple research and stakeholder meetings throughout the multi-year research and criteria development process; and opportunities for comments on the draft criteria and implementation guidance. If EPA insists upon taking any additional steps toward publishing final 304(a) criteria, it should conduct a more inclusive and thorough evaluation of the science and engage in additional stakeholder outreach before taking any final action. Such an approach would be appropriate given that there are no statutory or judicial deadlines compelling urgent action.

6. **If the agency instead wants to provide guidance (*e.g.*, 304(a)(2) information) to protect public health from exposure to algal toxins during recreation at freshwater and marine beaches, EPA should collaborate with states that have developed such guidance and publish a more useful, comprehensive Swimming Advisory document.**

EPA's draft document notes that "[a]pproximately 30 U.S. states have implemented cyanobacterial HAB guidelines for recreational waterways as of November 2015." *See* Draft Criteria at 10. The various guidelines appear to be more robust than EPA's document in terms of actions that can be taken to protect public health.

There are semi-quantitative strip tests that can indicate whether microcystin is present after an hour – these tests provide a sufficient basis for states to issue swimming advisories; however, they are not sufficient for establishing exceedances of 304(a) criteria.

Many natural waterways that are used for recreation are not monitored. The public would be better informed by plain language guidance that communicates the risk of swimming based on visual observations, rather than the more technical criteria or advisories that EPA is currently working on.

In many states, the agency responsible for administering the Clean Water Act is not the same as the agencies responsible for monitoring beaches and issuing swimming advisories. Existing state guidance documents include information on the role of multiple state agencies, decision trees based on visual observations of harmful algal blooms, steps needed to make data accessible to the public in as timely a fashion as possible, etc. Nevertheless, EPA should provide information to the states on how to issue and rescind swimming advisories.

[5] *See* Consent Decree, *NRDC v. Johnson*, No. 06-cv-4843 (C.D. Cal. lodged Sept. 4, 2008).

There are inherent risks associated with swimming in natural bodies of water. Any final document that EPA issues should address the severity of risk with increasing levels of algal toxins, which is important for appropriate risk communication.

7. Implementation of these levels as 304(a) criteria is going to be extremely complex, even more so than EPA's recommended ammonia criteria published in 2013 and only adopted by a handful of states primarily due to implementation issues. EPA should not promulgate these levels as 304(a) criteria until these implementation issues have been vetted.

The linkage between violations of these criteria and the discharge of nutrients from regulated point sources is indirect and highly complicated. Environmental conditions are a controlling factor. It is difficult to understand how the National Pollutant Discharge Elimination System (NPDES) and Total Maximum Daily Load (TMDL) programs will address the risks associated with recreation and exposure to algal toxins.

EPA acknowledges that pollutant loads and even targeted nutrient concentrations are not good predictors of *Microcystis* blooms. For instance, EPA notes (at 15) that "[s]everal environmental factors, including nutrient load, increased water temperature, salinity, pH, light intensity, and reduced mixing, provide competitive advantages to Microcystis related to other phytoplankton" and that a number of cyanobacterial species can produce cylindrospermopsin (at 16). EPA further notes that "Cylindrospermopsin provides a competitive advantage to cyanobacteria when phosphorus becomes scarce" (at 16). Finally, EPA also acknowledges that these blooms can occur naturally although scientists increasingly agree that the blooms have been increasing in recent decades (at 17).

As of today's date, the docket contains comments from some state agencies expressing concerns about implementation issues. For instance, the Florida Department of Environmental Protection[6] conducted inter-laboratory variability studies that showed the magnitude of measured microcystin varied by several orders of magnitude. Given this significant variability and imprecision, additional guidance is needed for both sampling and analysis protocols. Additionally, the Wyoming Department of Environmental Quality, Water Quality Division points out that EPA has not provided guidance about how these levels should be used in placing waters on the Section 303(d) list of impaired waters. That agency has expressed concerns about, among other things, whether EPA anticipates that states identify the cause of impairments as cyanotoxins or excess nutrients.[7] On that score, EPA has not provided any guidance on how waters placed on the 303(d) list due to cyanotoxins should be managed.

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[6] Whiting, David, Florida Department of Environmental Protection. Letter to John Ravenscroft, US EPA. February 22, 2017. 9 pages.

[7] Frederick, Kevin, Wyoming Department of Environmental Quality. Letter to Health and Ecological Criteria Division. February 13, 2017. 4 pages.

In light of these and other uncertainties, additional analysis is warranted to determine how recommended criteria are to be implemented before EPA moves forward with finalizing any recommendations.

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In conclusion, EPA should reopen the public comment period, allow the public to provide additional scientific views, and address all significant concerns (including those raised herein) before publishing any final recommended values under either Section 304(a)(1) or Section 304(a)(2) of the Clean Water Act. We appreciate the opportunity to offer these comments. Should you have any questions, we welcome the opportunity to discuss with you further.

Respectfully submitted,

Agricultural Retailers Association
American Dairy Coalition
American Farm Bureau Federation
Arizona Pork Producers Associations
California Pork Producers Association
Colorado Pork Producers Association
Dairy Producers of Utah
Exotic Wildlife Association
Idaho Dairy Association
Illinois Farm Bureau Federation
Illinois Corn Growers Association
Indiana Pork Advocacy Coalition
Iowa Corn Growers Association
Iowa Pork Producers Association
Kansas Corn Growers Association
Kansas Pork Association
Michigan Corn Growers Association
Minnesota Corn Growers Association
Missouri Dairy Association
National Alliance of Forest Owners
National Associate of State Departments of Agriculture
National Association of Wheat Growers
National Cattlemen's Beef Association
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Pork Producers Council
North Dakota Corn Growers Association
Ohio Agribusiness Association
Ohio Corn and Wheat Growers Association
Ohio Pork Council
Oregon Dairy Farmers Association
Texas Dairy Association
Texas Poultry Federation
The Fertilizer Institute
United Egg Producers
Upstate Niagara Cooperative